

Fig. 1

cancer\_protocols\_INSTANCE\_00039 [instance of Cancer\_Clinical\_Protocol]

CALGB 49802

mgk

Phase III Study of Adriamycin/Taxotere vs  
Adriamycin/Cytoxan for the Adjuvant  
Treatment of Node Positive or High Risk  
Node Negative Breast Cancer

M. G. Fullic

Reference  
MUSC PRN web page

CALGB 49802 Level 1

Initial Criteria/Values

Initial Name

CALGB 49802

Client/State Name

Initial Status

Initial Name

Client/State Name

Tumor of any size with direct extension to chest wall or skin (T4)

Patient is pregnant or nursing

- ❖ Histologically or cytologically confirmed invasive breast cancer
- ❖ 1-3 histologically involved axillary lymph nodes
- ❖ No evidence of metastatic disease (M0)
- ❖ Absolute neutrophil count at least 1,500/mm<sup>3</sup>
- ❖ Platelet count at least 100,000/mm<sup>3</sup>
- ❖ Left ventricular ejection fraction at rest at least 45% by MUGA
- ❖ Bilirubin no greater than 1.2 times upper limit of normal (ULN)
- ❖ Age 18-70
- ❖ Effective contraception required of fertile women
- ❖ No prior chemotherapy
- ❖ No prior radiotherapy
- ❖ No concurrent estrogen therapy

212

210

Fig. 2

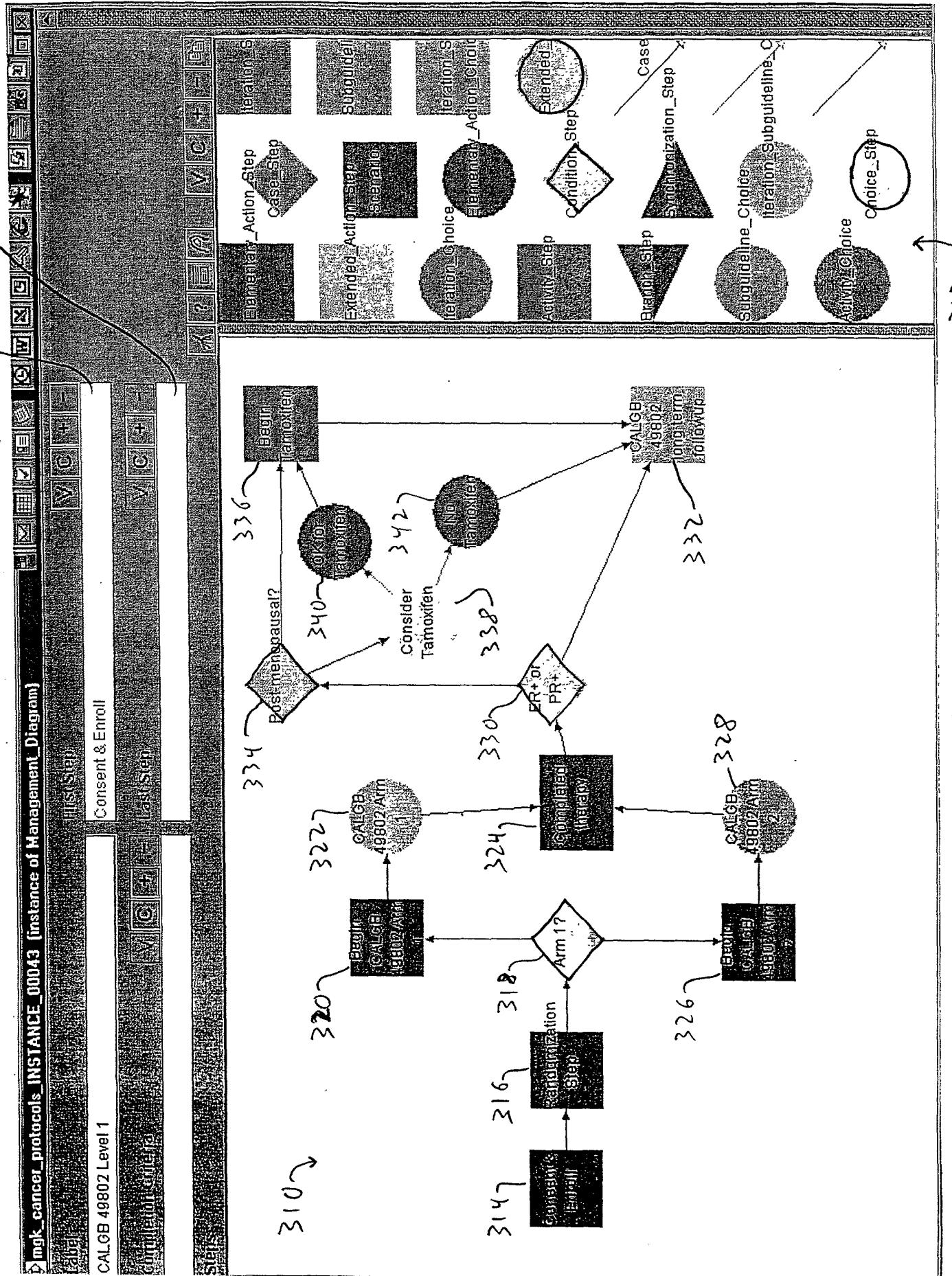


Fig. 3

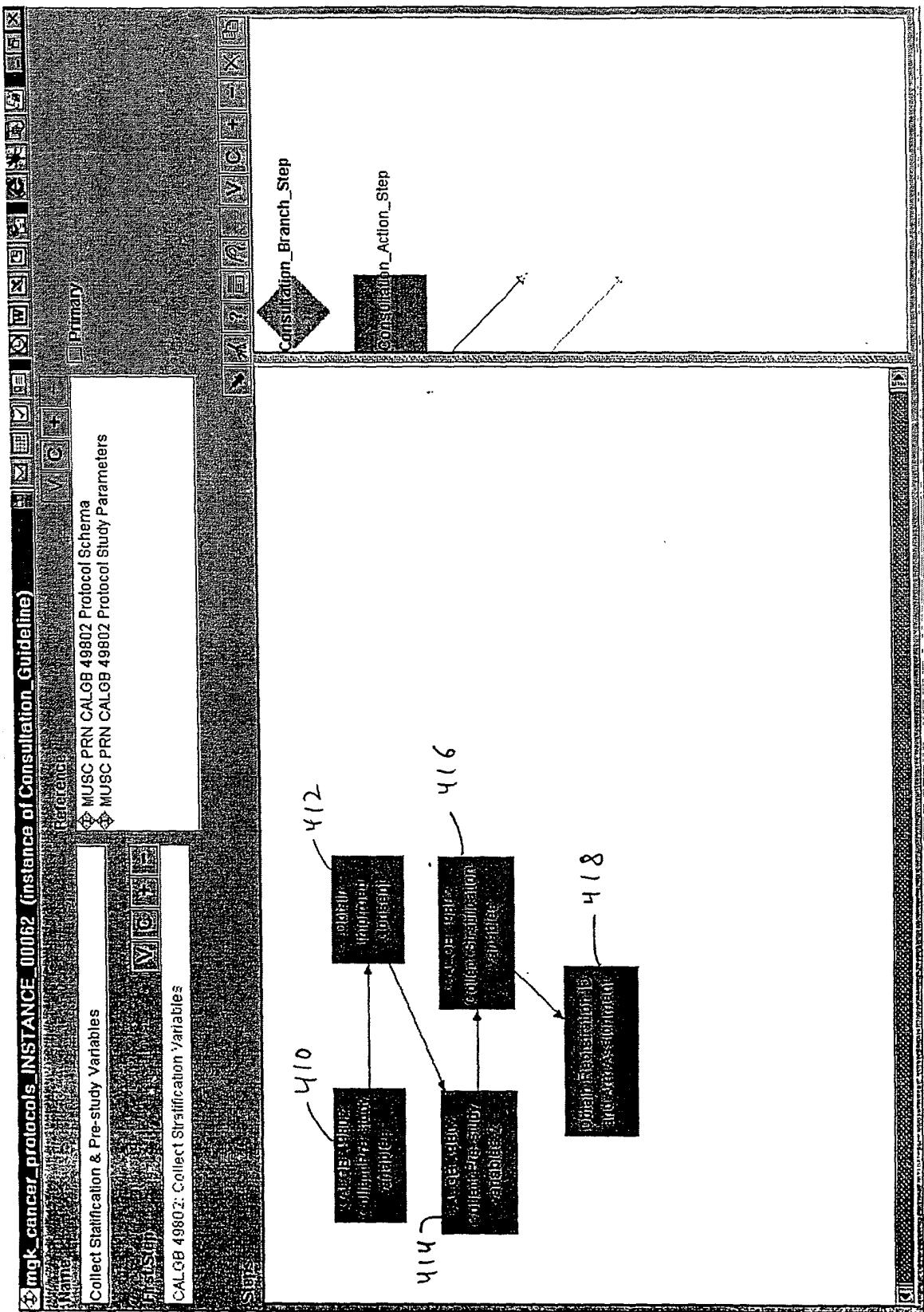
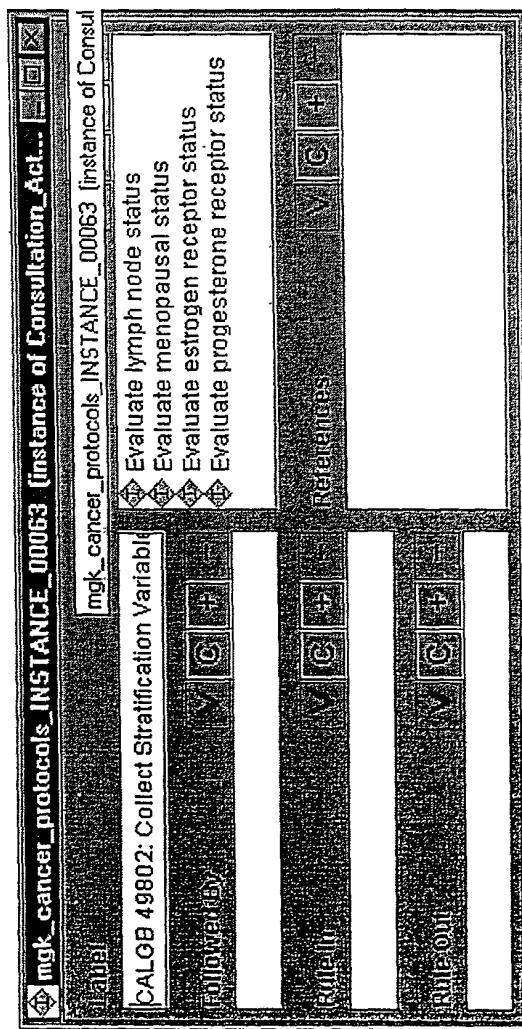


Fig. 4



6  
5  
4

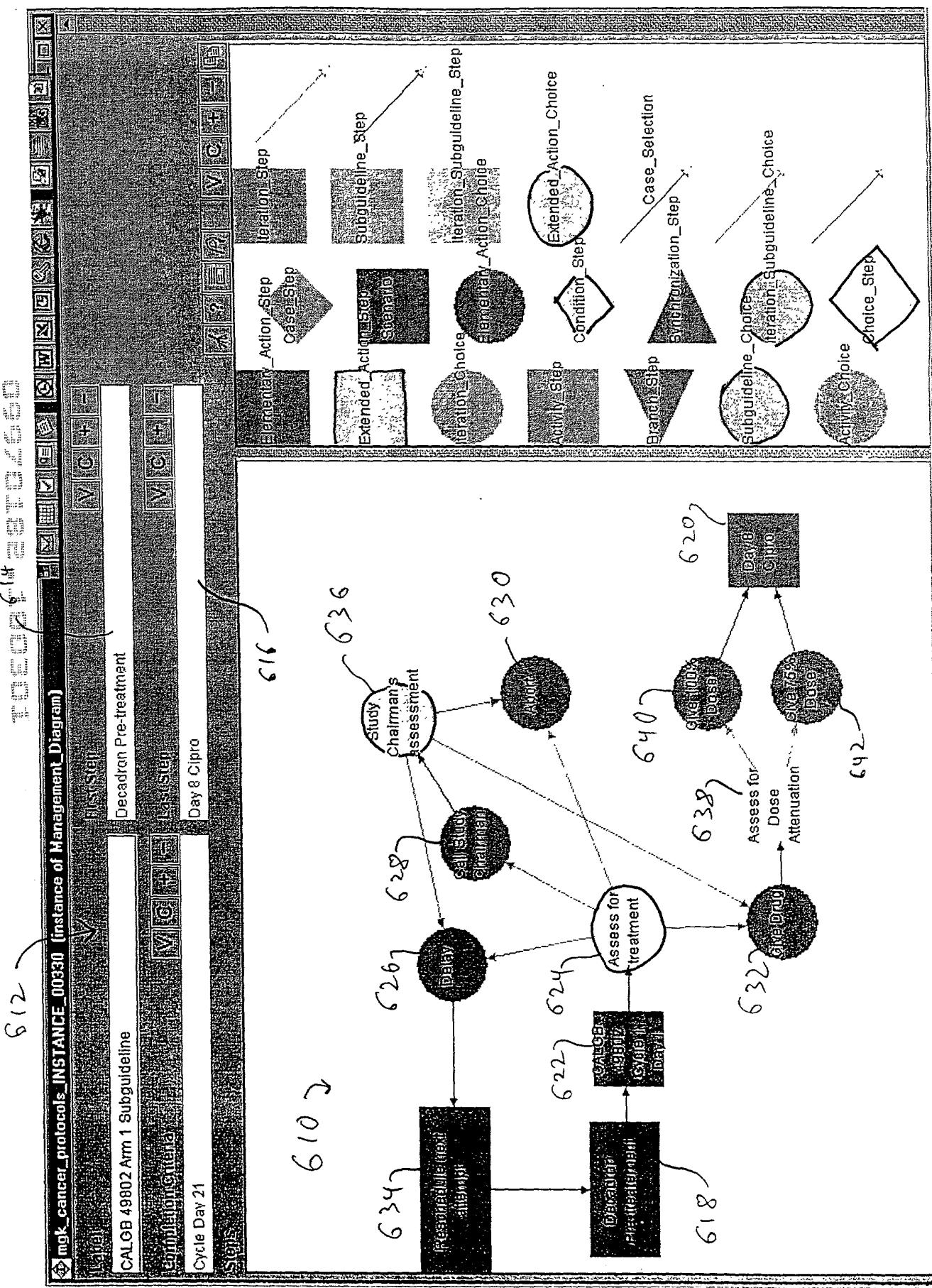


Fig. 6

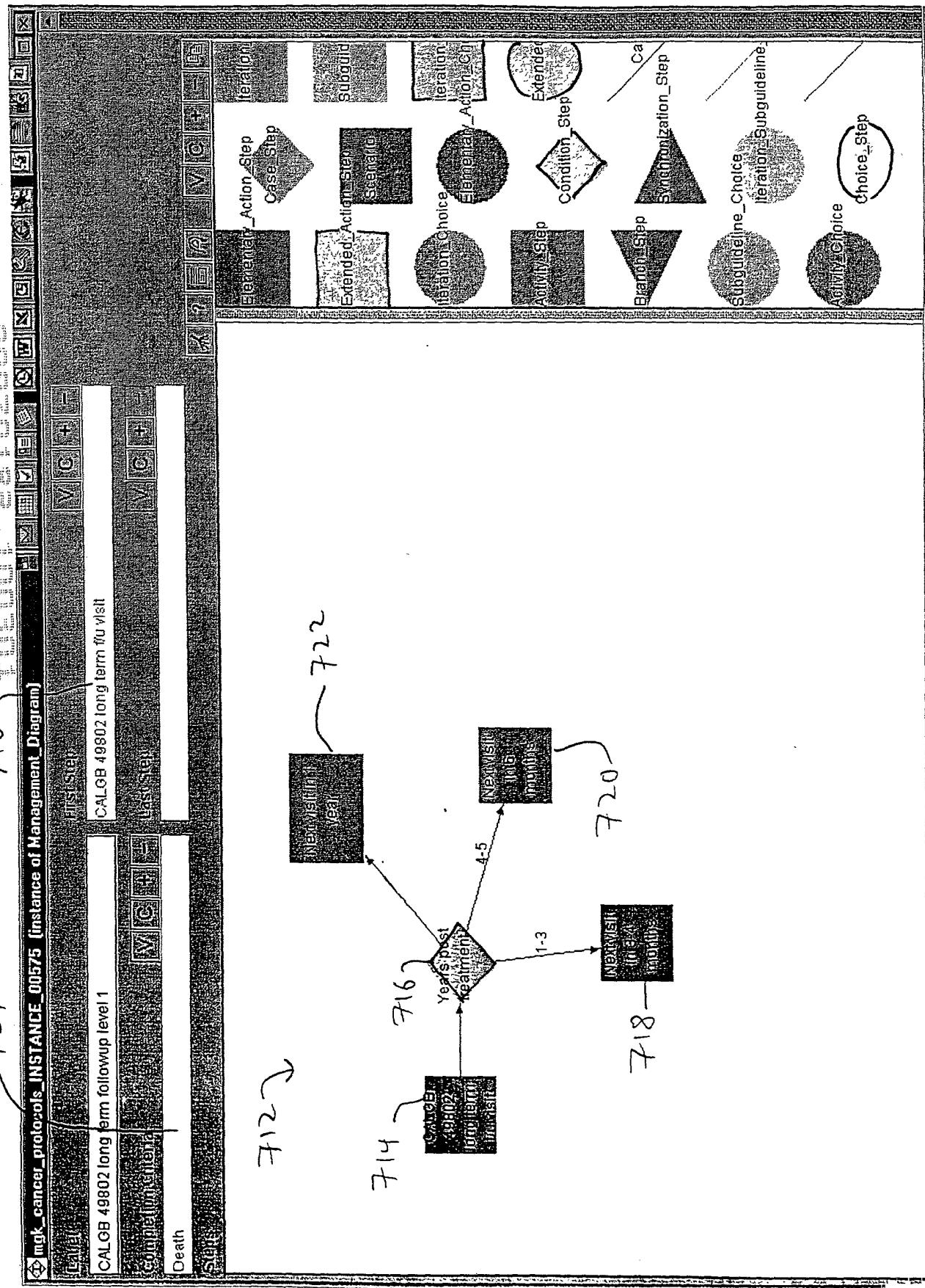


Fig. 7

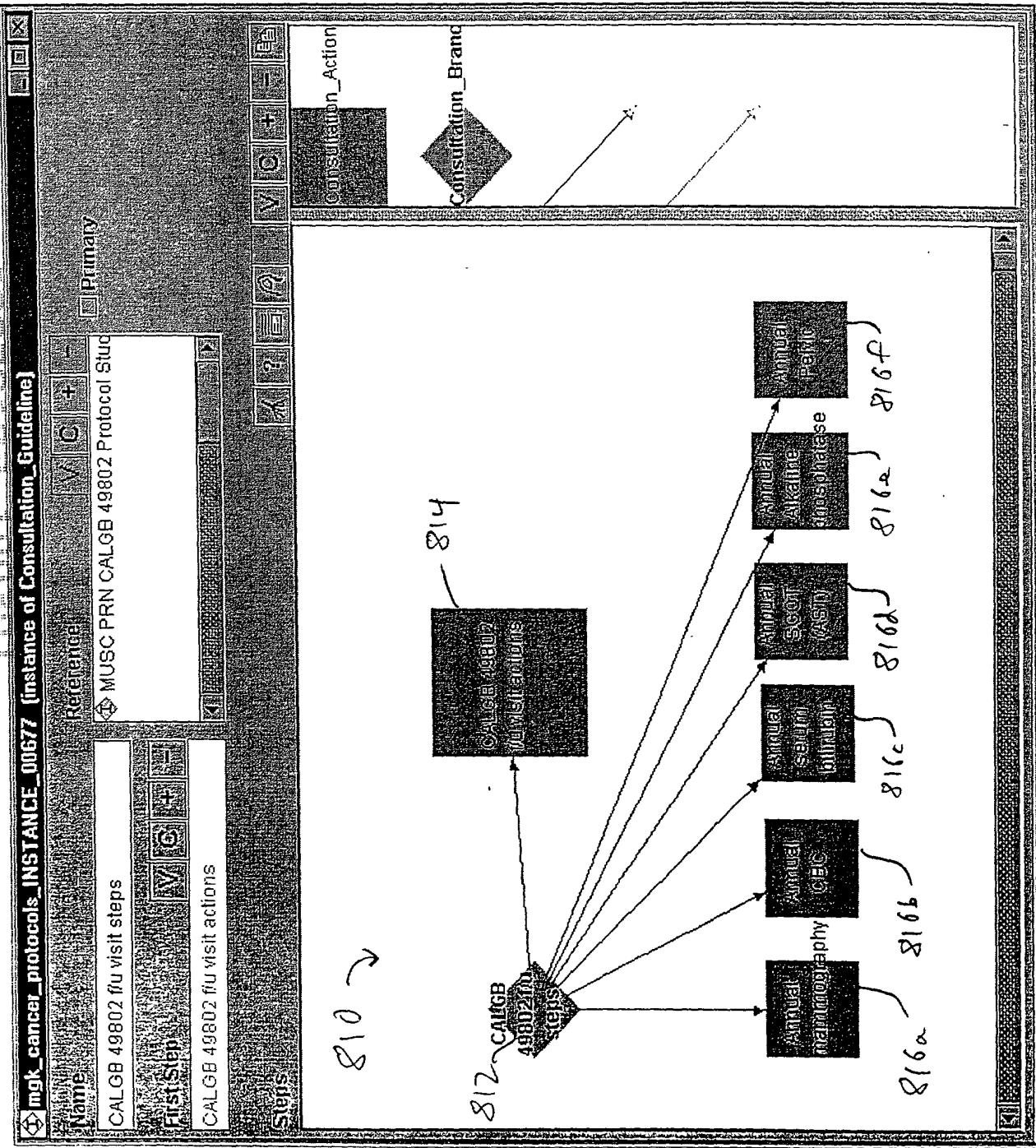


Fig. 8

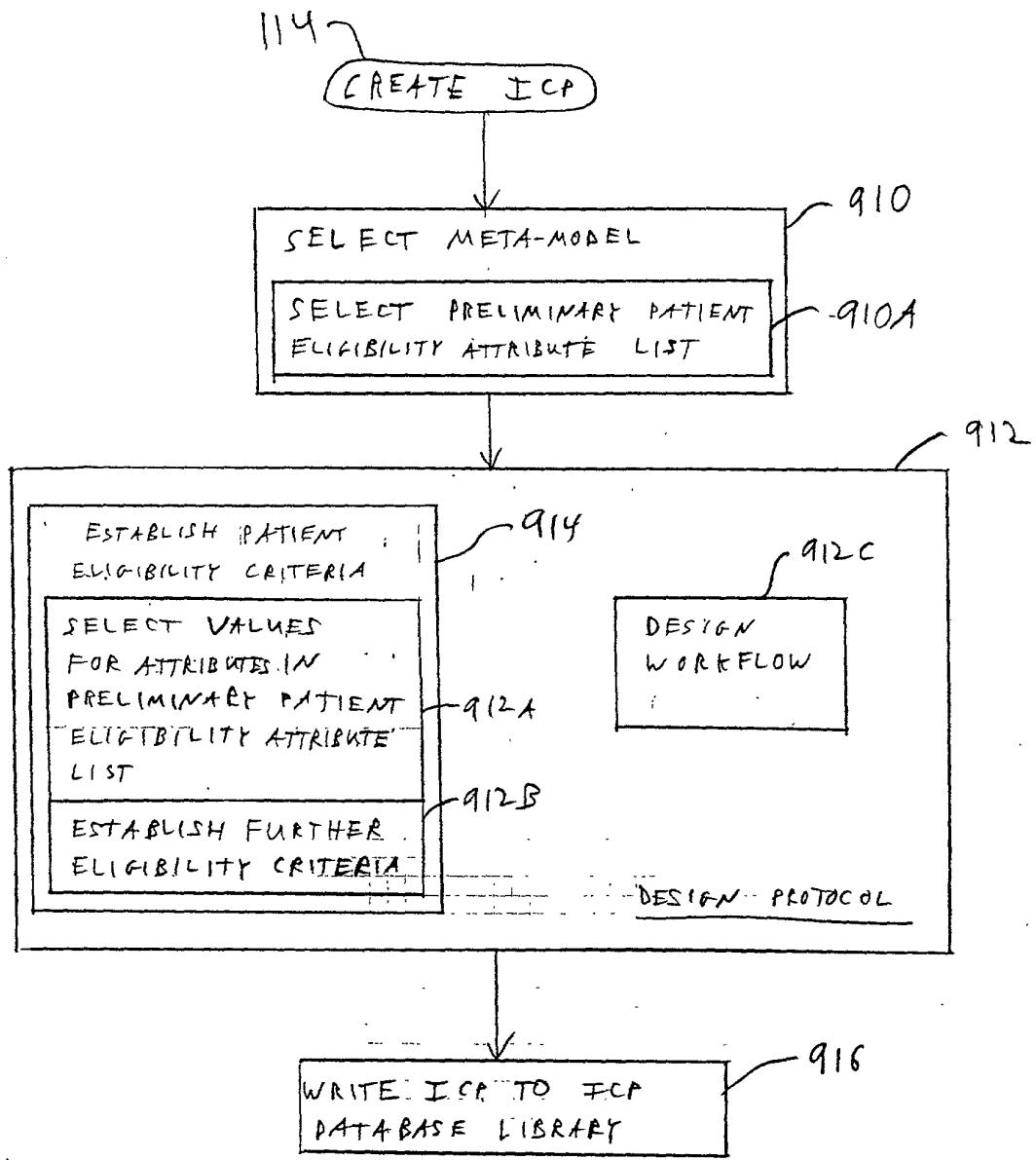


Fig. 9

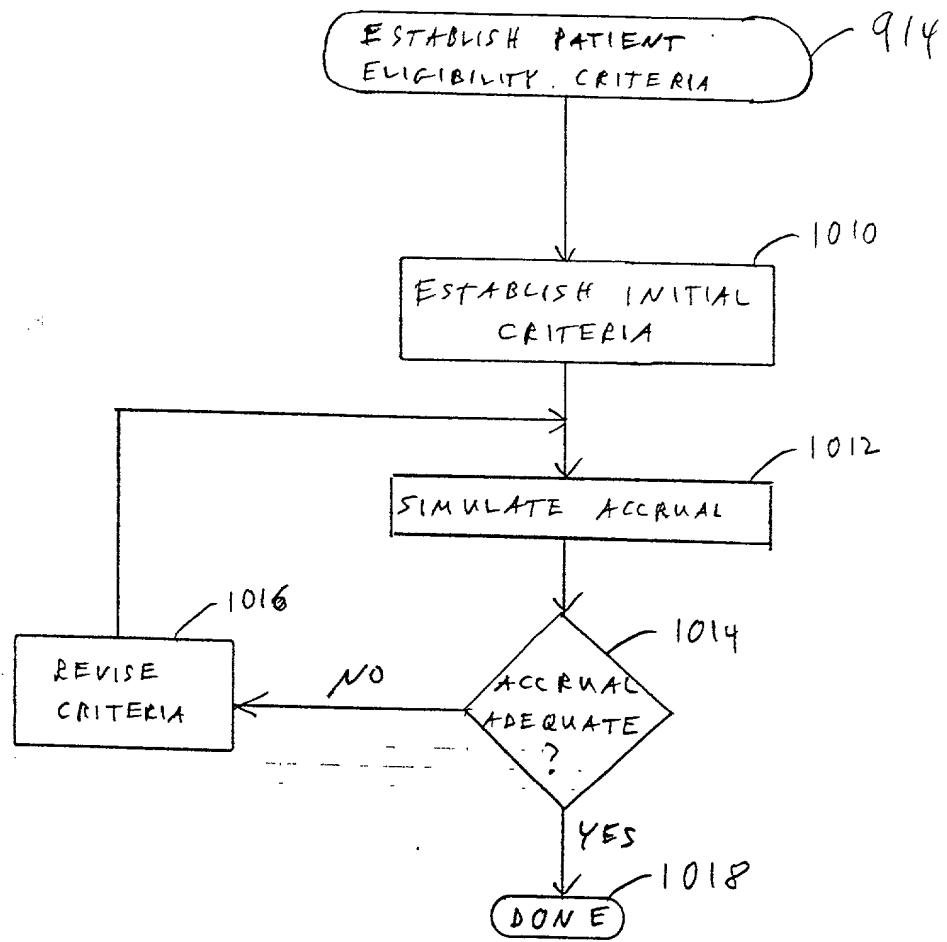


Fig. 10

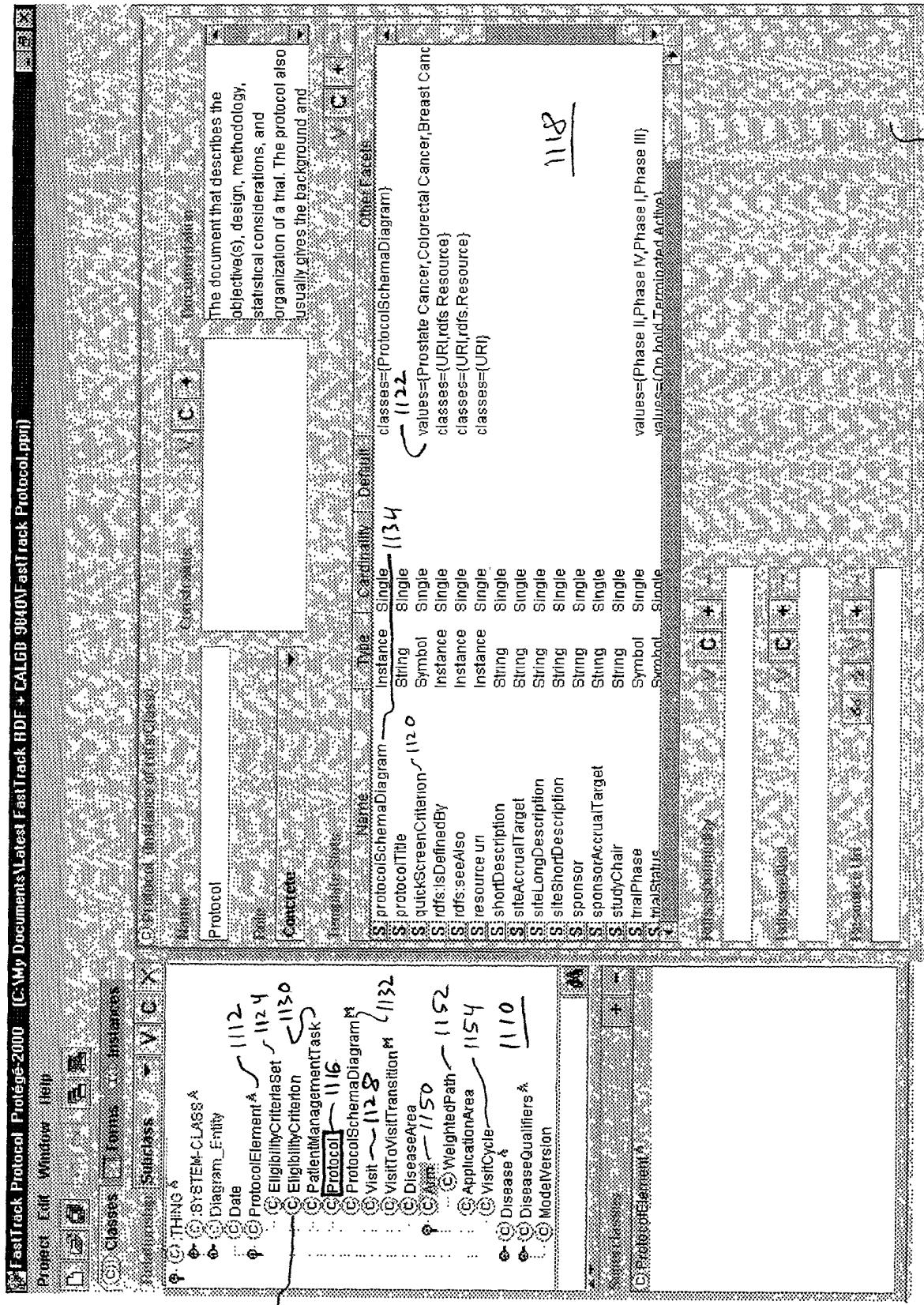
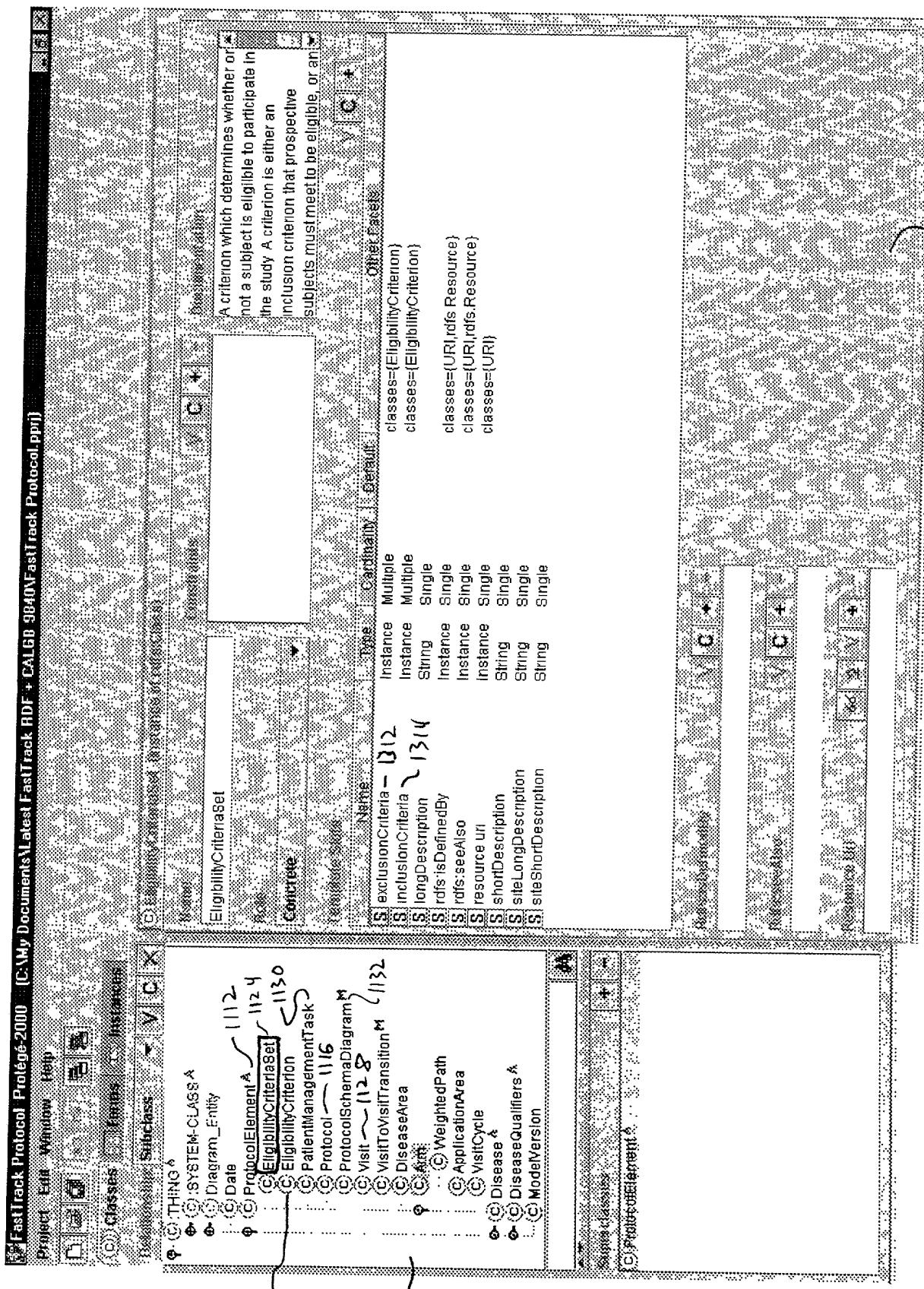


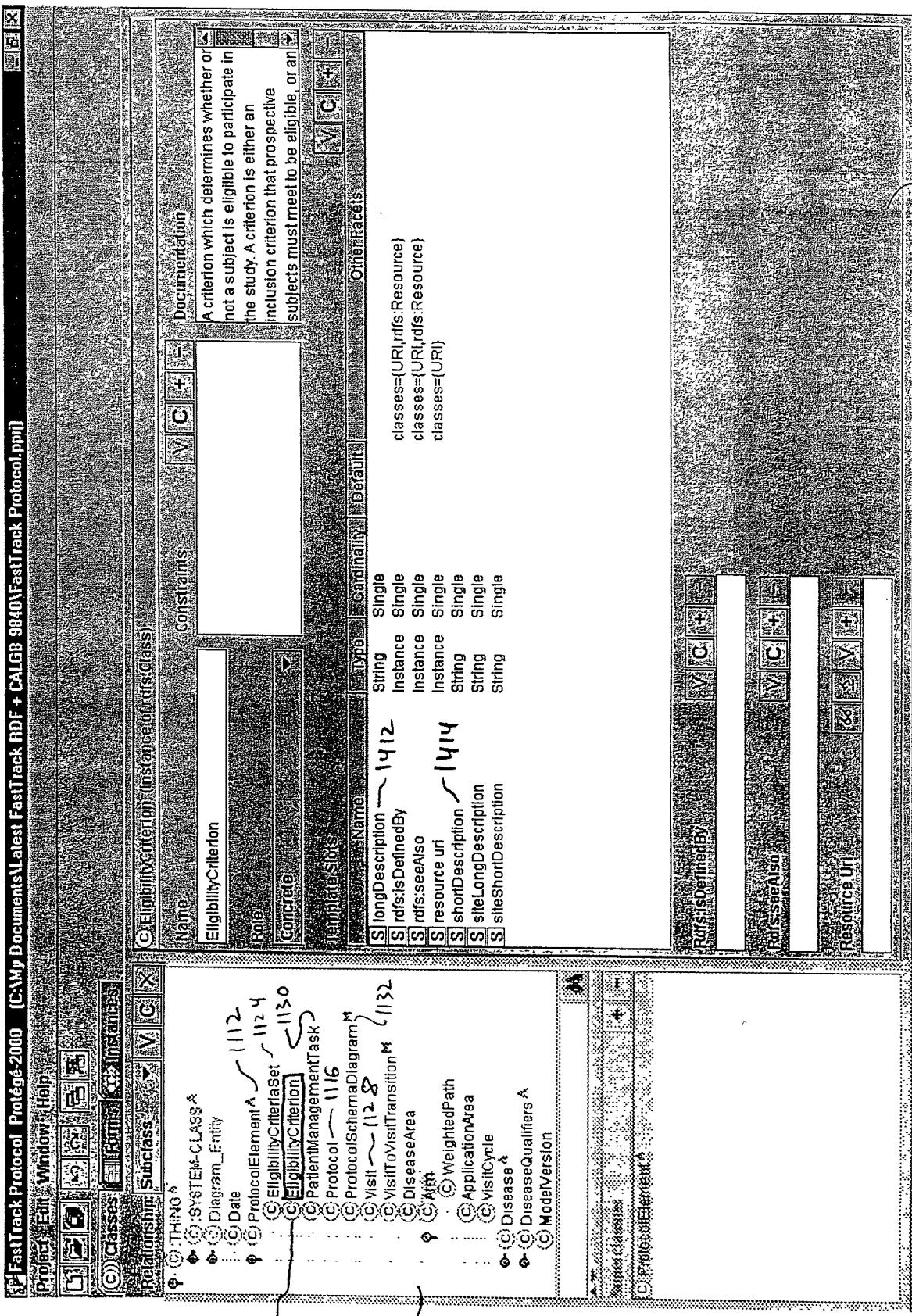
Fig. 11

FastTrack Protocol INSTANCE_00212 [Instance of Protocol]	
ProtocolTitle	Version
A Phase III Study of Paclitaxel via Weekly 1-Hour Infusion w/	Update #1
ProtocolIdentifier	VersionDate
CALGB 9840	December 15
OfficialSourceDocument	EligibilityCriteriaSet
<a href="http://prn.musc.edu/research/protocol/deptmed/divhono/sbr">http://prn.musc.edu/research/protocol/deptmed/divhono/sbr</a>	  
ShortDescription	CALGB 9840 Eligibility Criteria
CALGB 9840	1212
StudyChair	
Andrew D. Seidman, M.D.	
Sponsor	StudyDescription
CALGB	
QuickScreenCriterion	
Breast Cancer	
ProtocolObjectives	
To compare "standard" (S) paclitaxel at 175 mg/m <sup>2</sup> via 3-hour infusion every 3 weeks to "dose-dense" (DD) paclitaxel at 80 mg/m <sup>2</sup> via 1-hour infusion every week	
TrialStatus	ProtocolStatus
Active	Open for accrual
TrialPhase	InitialType
Phase III	Cooperative group
	1210
	1214
	CALGB 9840 Schema
	ProtocolSchemaDiagram
	  
	Fig. 12



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Fig. 13



1410

Fig. 14

FastTrack Protocol INSTANCE_00074 [Instance of EligibilityCriteriaSet]	
<b>ShortDescription</b>	<b>LongDescription</b>
<b>CALGB 9840 Eligibility Criteria</b>	
<b>InclusionCriteria</b>	<b>ExclusionCriteria</b>
<input checked="" type="checkbox"/> Female Breast adenocarcinoma that is inoperable, recurrent, or metastatic More than 4 weeks since last chemotherapy More than 6 weeks since treatment with nitrosoureas, melphalan, or More than 4 weeks since last hormonal therapy OR tumor measurable Age $\geq 18$ Measurable disease Granulocytes $\geq 1,500 / \mu l$ Platelet count $\geq 100,000 / \mu l$ Creatinine $\leq 2.0 \text{ mg/dl}$ Bilirubin within institutional normal limits SGOT (AST) $\leq 3X$ upper limits of normal Greater than 2 weeks from prior surgery	<input checked="" type="checkbox"/> CNS metastases if untreated or symptomatic $\rightarrow 15/0$ Prior taxane for metastatic or locally-advanced breast cancer Prior taxane in adjuvant setting where patient remained disease free Lepiomeningeal carcinoma
<b>SiteShortDescription</b>	<b>Rdfs:isDefinedBy</b>
	<input checked="" type="checkbox"/> <a href="#">http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&amp;db=pubmed&amp;list_uids=15102000&amp;dopt=Abstract</a>
<b>Rdfs:seeAlso</b>	<b>Resource Uri</b>
	<input checked="" type="checkbox"/> <a href="#">http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&amp;db=pubmed&amp;list_uids=15102000&amp;dopt=Abstract</a>

Fig. 15

FastTrack Protocol INSTANCE_00073 [Instance of EligibilityCriterion]	
<b>ShortDescription</b>	
1610	CNS metastases if untreated or symptomatic
<b>LongDescription</b>	
1612	<p>Patients with central nervous system metastases are eligible only if the patient has completed cranial irradiation at least 6 months prior, is currently asymptomatic, and is not currently receiving corticosteroids for this condition.</p>
<b>SiteShortDescription</b>	
<b>SiteLongDescription</b>	

1610 →

1612 →

Fig. 16

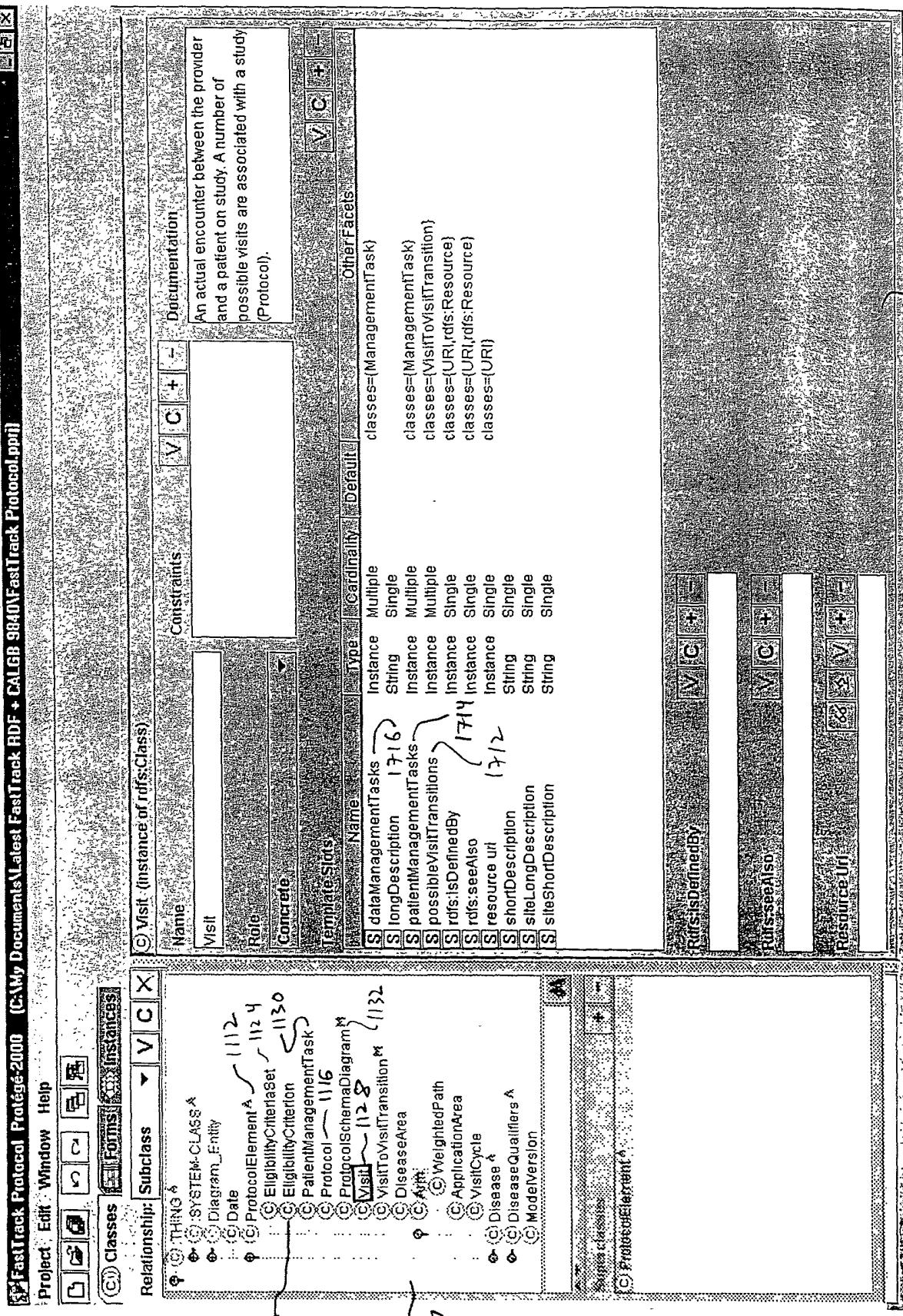


Fig. 17

FastTrack Protocol INSTANCE_00014 [instance of Visit]	
<b>ShortDescription</b>	Arm A Treatment Visit
<b>DataManagementTasks</b>	<ul style="list-style-type: none"> <li>Submit Form C-116 ~ 1818</li> <li>Submit Form C-118</li> <li>Submit Form C-080</li> <li>Submit Form C-344 + Form C-080 (*)</li> <li>Submit Form C-344 + Form C-272 (*)</li> <li>Submit Form C-113 (*)</li> <li>Submit Form C-260 (*)</li> <li>Submit Form C-300 (*)</li> </ul>
<b>PossibleVisitTransitions</b>	<ul style="list-style-type: none"> <li>Arm A Treatment to Arm A Treatment Reinf #1 ~ 1810</li> <li>Arm A Treatment to Long Term Followup</li> <li>Arm A Treatment Visit to Arm A Treatment Visit ~ 1812</li> </ul>
<b>DataManagementTasks</b>	<ul style="list-style-type: none"> <li>Confirm no G-CSF given in past 24 hours</li> <li>Give Dexamethasone 10 mg IV, 30 minutes</li> <li>Give Diphenhydramine 50 mg IV, 30 minutes</li> <li>Give Cimetidine 300 mg IV, 30 minutes</li> <li>Give anti-emetics (*)</li> <li>Give Arm A Paclitaxel treatment ~ 1816</li> <li>Give G-CSF (*)</li> <li>Evaluate Patient Response</li> <li>Schedule next visit</li> </ul>
<b>LongDescription</b>	<p>Arm A of the CALG 9840 consists of treatment with Paclitaxel 175 mg/m<sup>2</sup> administered as a 3 hour infusion intravenously every three weeks. One cycle is equivalent to one infusion. Treatment cycles will be repeated every 21 days as long as the patient has stable or responding disease. Granulocyte count must be <math>\geq 1500/\mu\text{l}</math> and platelet count must be <math>\geq 100,000/\mu\text{l}</math> on day 1 of each cycle. Patients should receive a minimum of two cycles of therapy, unless there is rapid disease progression (<math>\geq 50\%</math> increase in product of bi-dimensional measurements).</p>
<b>SiteLongDescription</b>	
<b>SiteShortDescription</b>	

Fig. 18

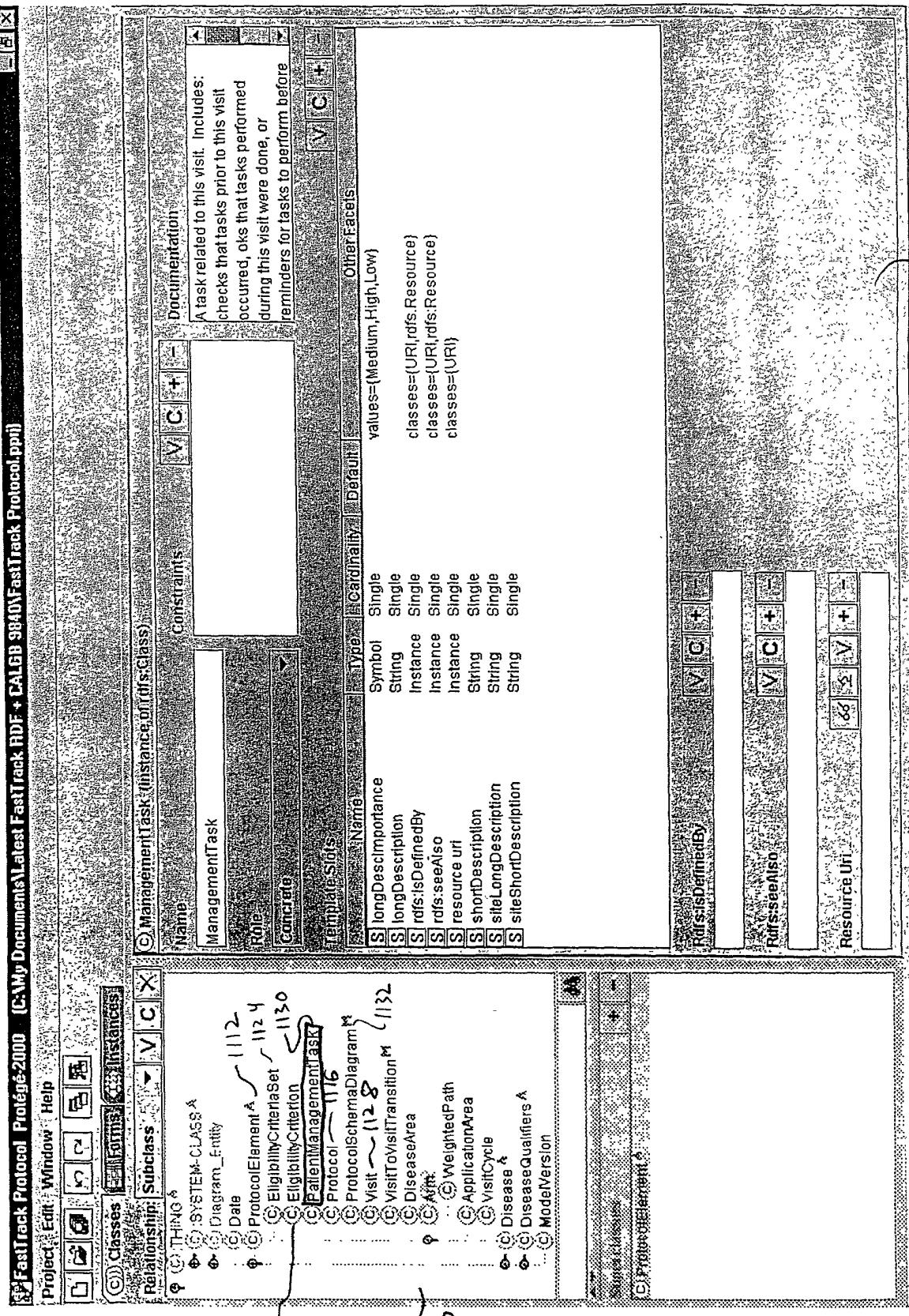


Fig. 19

10

## FastTrack Protocol\_INSTANCE\_00206 [instance of ManagementTask]

### ShortDescription

Give Arm A Paclitaxel treatment

### LongDescription

Give Paclitaxel 175 mg/m<sup>2</sup> IV, 3 hours. This treatment is given to patients in Arm A of the CALGB 9840 protocol. It is given once every 3 weeks. One cycle is equivalent to one infusion. Granulocyte count must be  $\geq 1500/\mu\text{l}$  and platelet count must be  $\geq 100,000/\mu\text{l}$  on day 1 of each cycle in order to proceed with the Paclitaxel infusion. Patients must receive the pre-medication prior to Paclitaxel infusion. If either the granulocyte or platelet count are not adequate, do not continue with treatment. Patients should receive a minimum of 2 cycles unless there is rapid disease progression.

Expected toxicities:

Dose Modifications:

### SiteLongDescription

Fig. 20

FastTrack Protocol INSTANCE\_001 96 (Instance of ManagementTask)

ShortDescription	Submit Form C-116	
LongDescription	Submit CALGB Advanced Breast Cancer Followup-form (C-116) every two cycles while on protocol therapy, at 6 & 12 months after end of treatment, at disease progression or initiation of non-protocol therapy.	
StartEndDescription		
SiteStartEndDescription		

Fig. 21

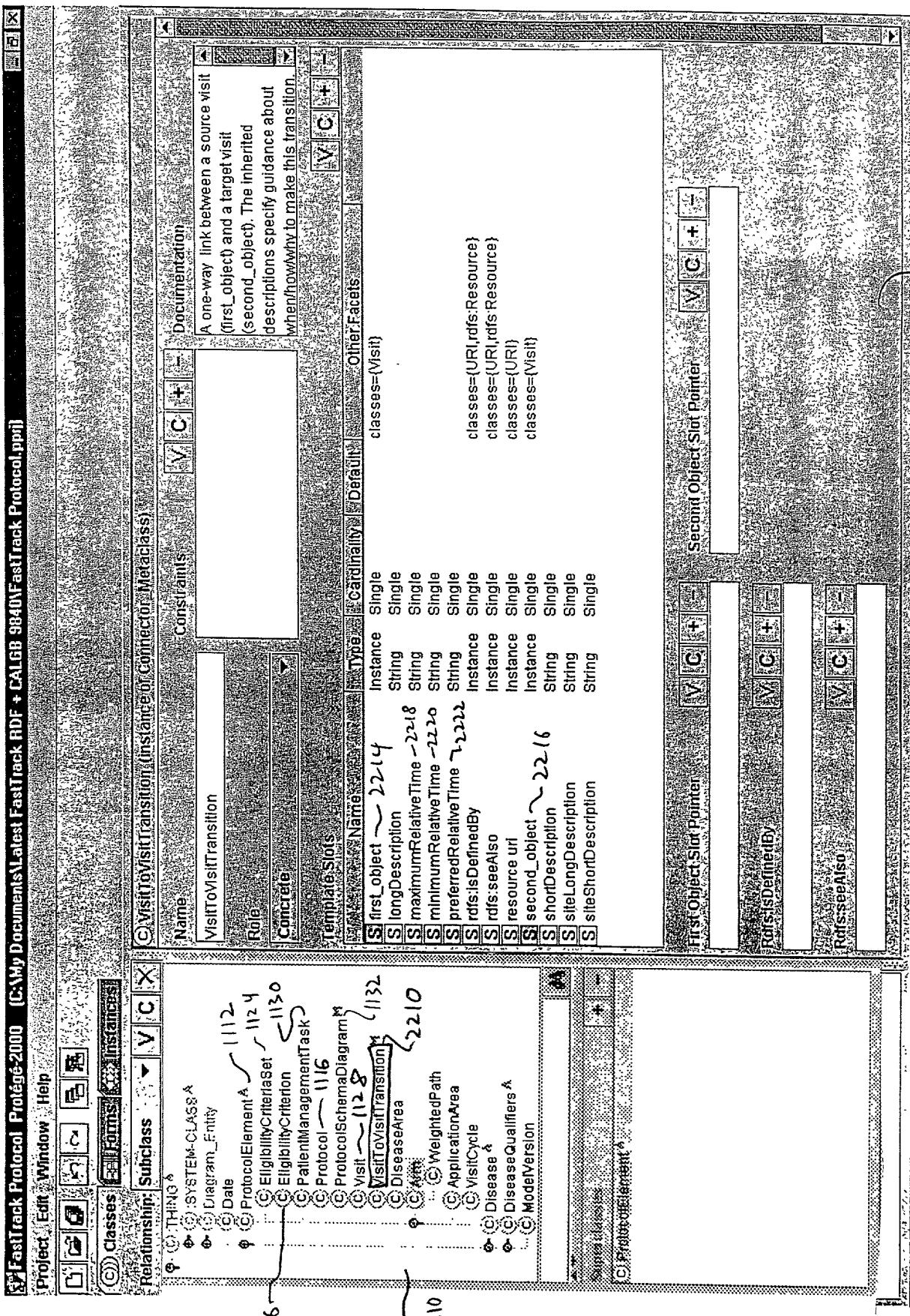


Fig. 22

1818 ✓

FastTrack Protocol INSTANCE\_00023 (Instance of Visit/Visit Transition)

ShortDescription	PreferredRelativeTime			
Arm A Treatment to Arm A Treatment Retry #	7			
First Object	V	G	+	MaximumRelativeTime
Arm A Treatment Visit	7			
Second Object	V	C	+	MinimumRelativeTime
Arm A Treatment Retry #1	7			
LongDescription				
<p>If either granulocyte or platelet count are not adequate, blood counts should be repeated weekly and treatment should be instituted when there has been hematologic recovery. Patients receiving G-CSF are not eligible for re-treatment unless they have been off G-CSF for a minimum of 24 hours.</p>				
SiteOnlyDescription <input checked="" type="checkbox"/> IsPreferredTransition				
SiteShortDescription				

2310

Fig. 23

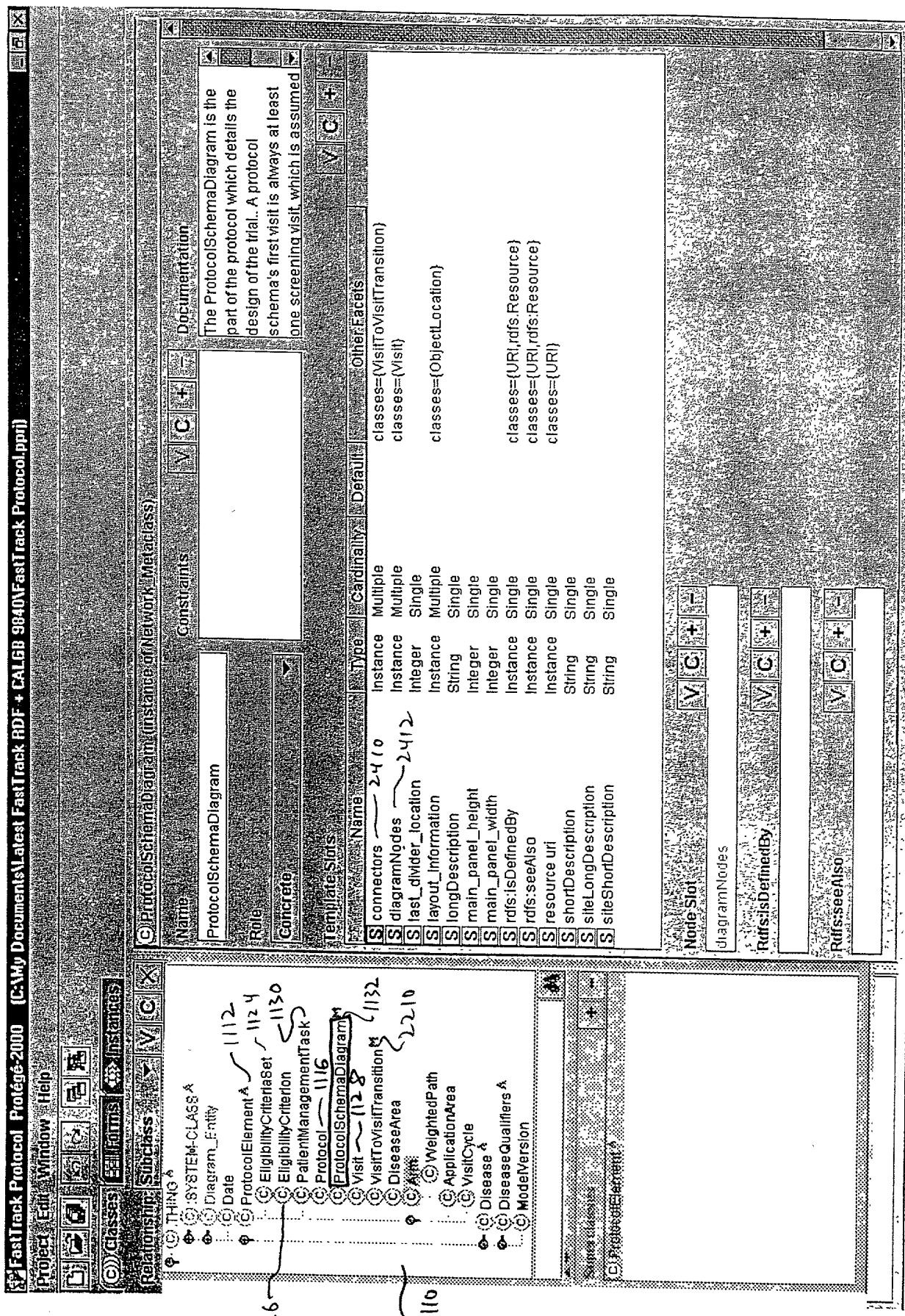
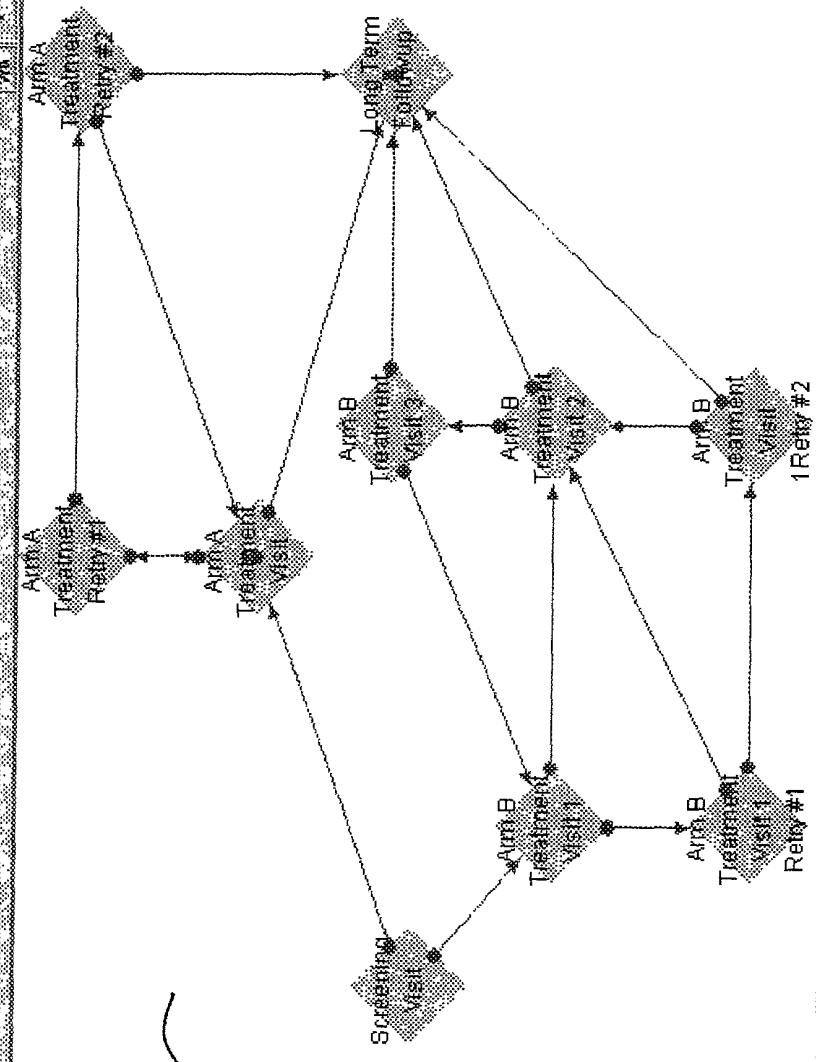


Fig. 24

FastTrack Protocol\_INSTANCE\_00008 [instance of ProtocolSchemaDiagram]



2516

2512

2514

2510

CALGB 9840 Schema

- Screening to Arm A Treatment Visit
- Screening to Arm B Treatment Visit
- Arm A Treatment to Arm A Treatment Retty #1
- Arm A Retty #1 to Arm A Treatment Visit
- Arm A Treatment Retty #1 to Arm A Treatment Retty #2
- Arm A Treatment Retty #2 to Arm A Treatment Visit
- Arm B Treatment to Arm B Treatment Retty #1
- Arm B Retty #1 to Arm B Treatment Visit
- Arm B Treatment Retty #1 to Arm B Treatment Retty #2
- Arm B Treatment Retty #2 to Arm B Treatment Visit

Fig. 25

ANONYMIZED  
TO CENTRAL  
OPERATIONAL DB

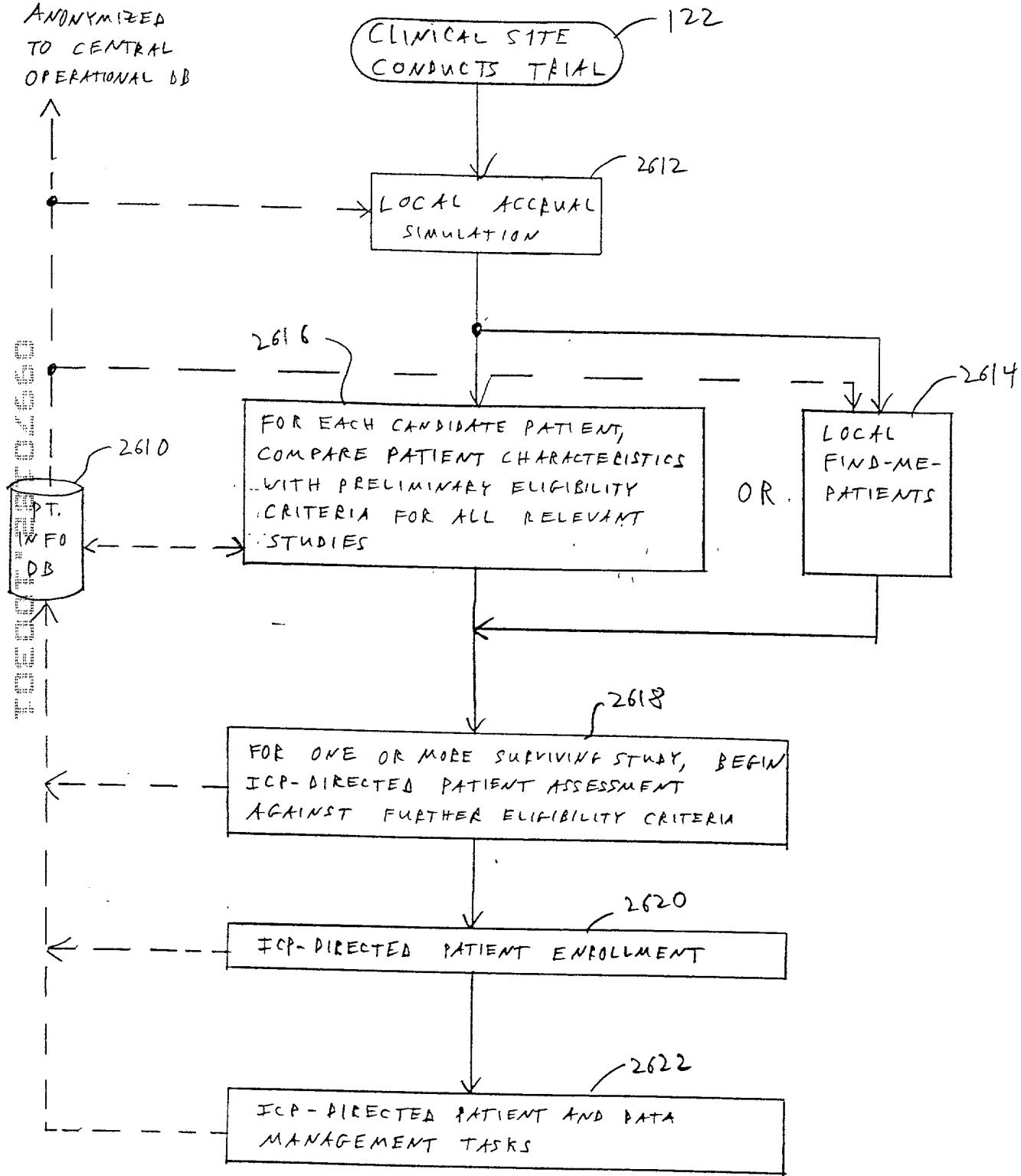


Fig. 26

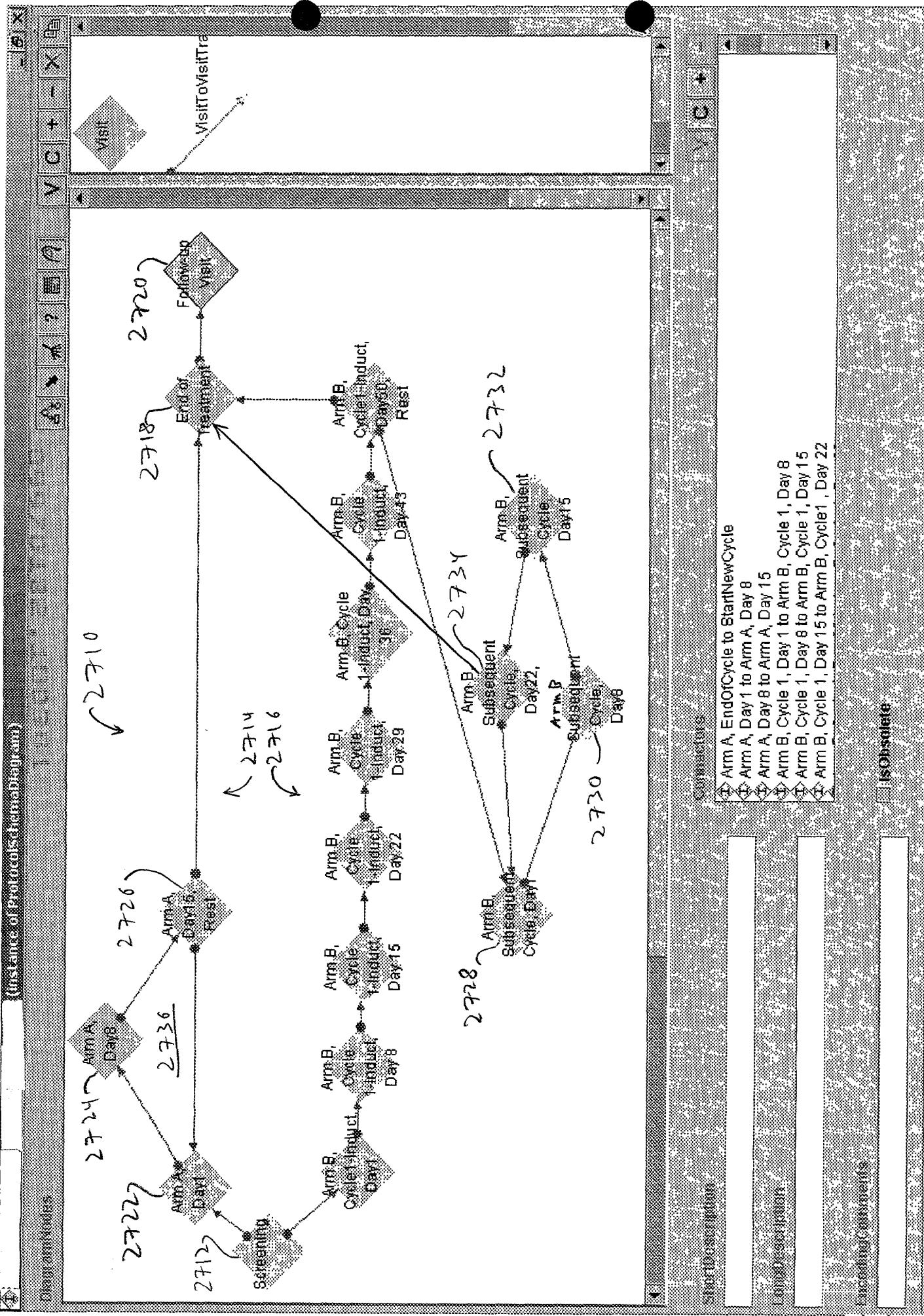


Fig. 27

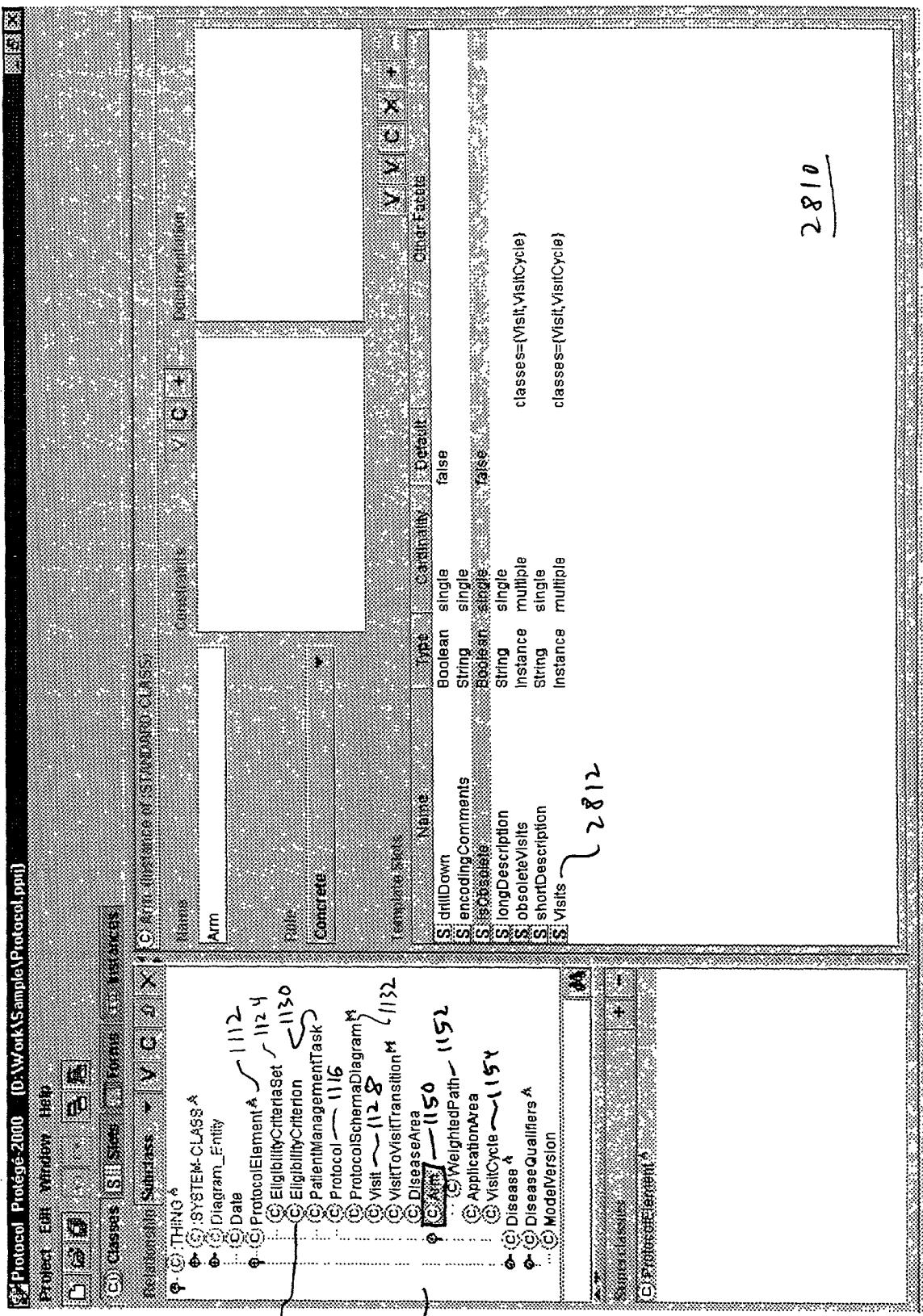


Fig. 28

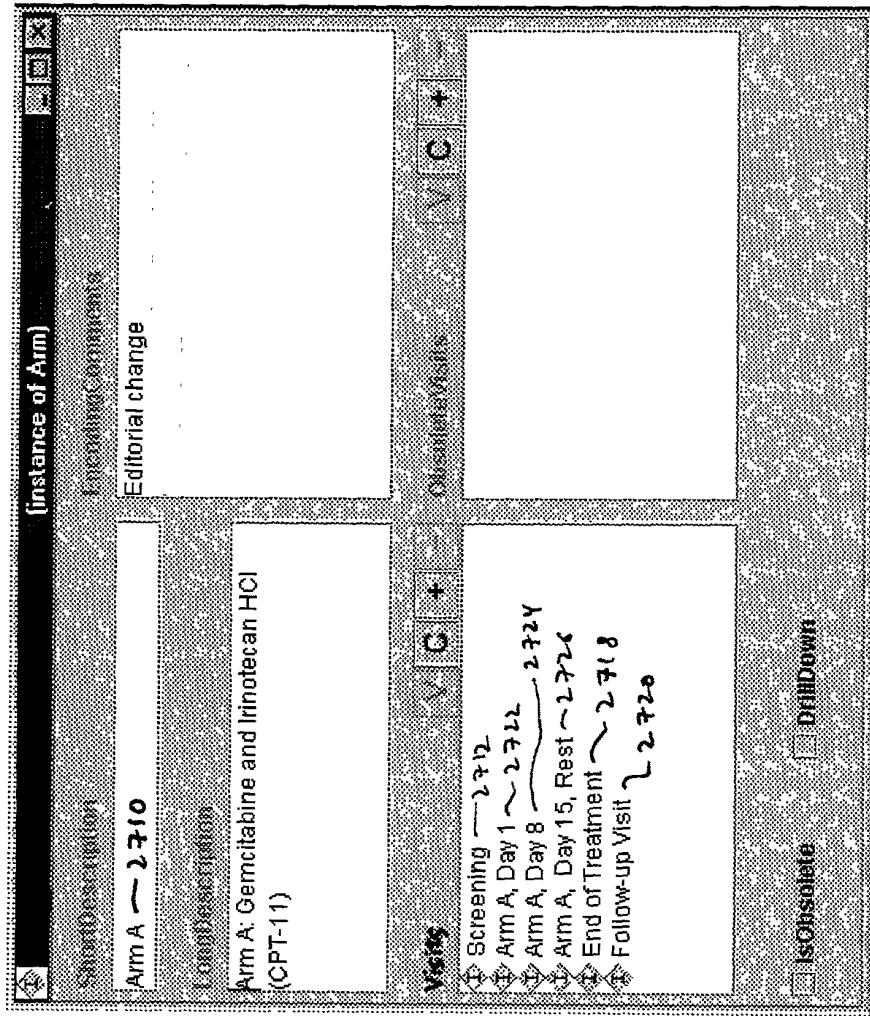


Fig. 24

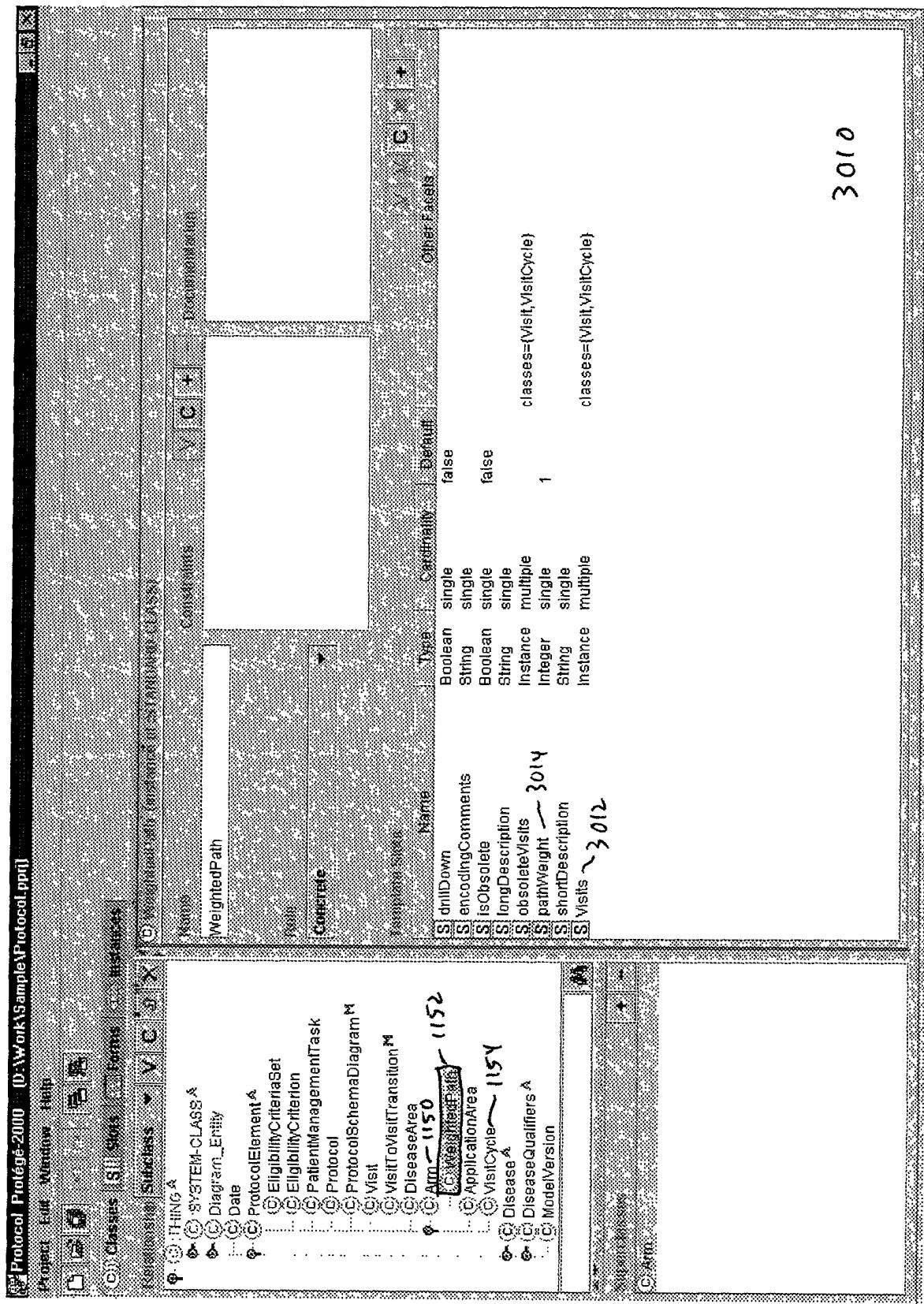


Fig. 30

3110

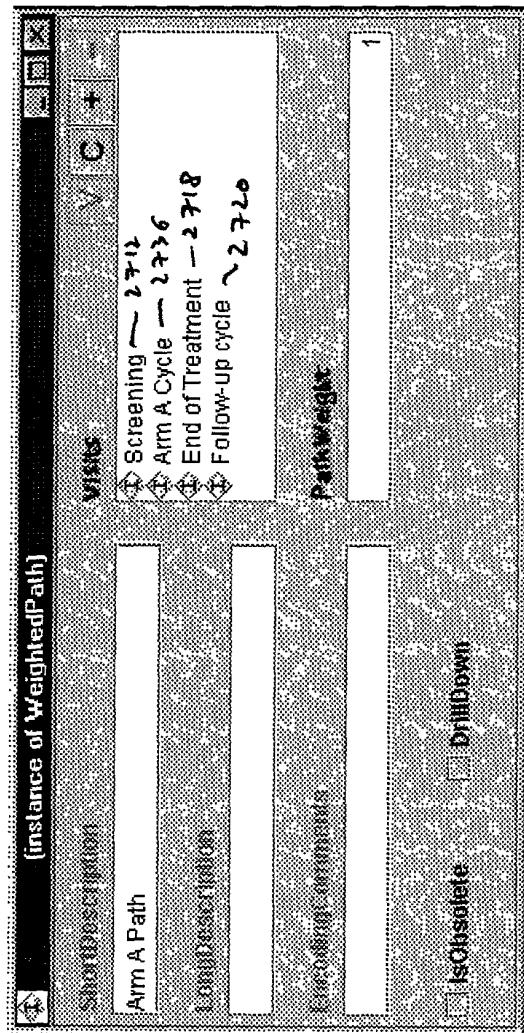


Fig. 31

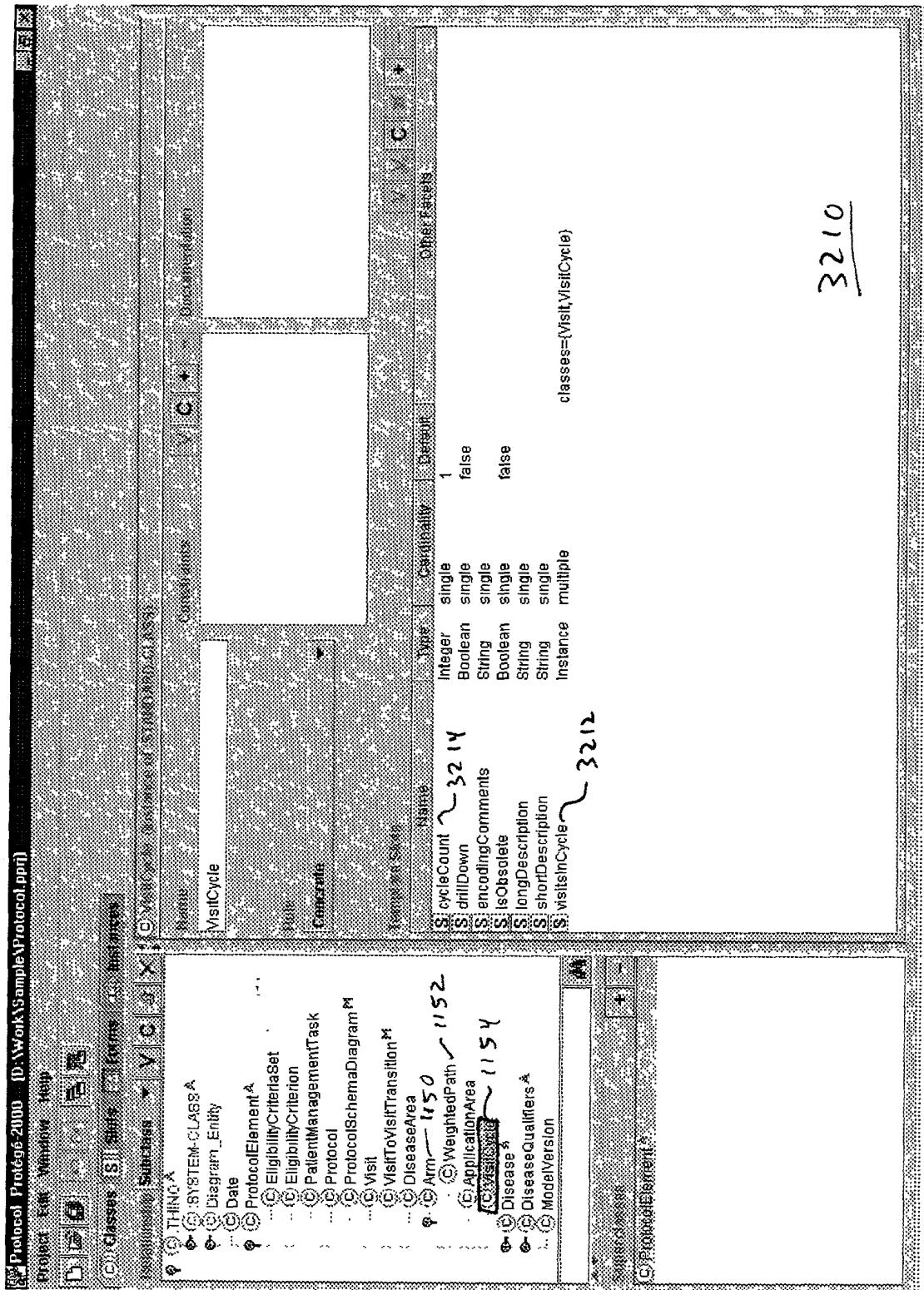


Fig. 32

2736

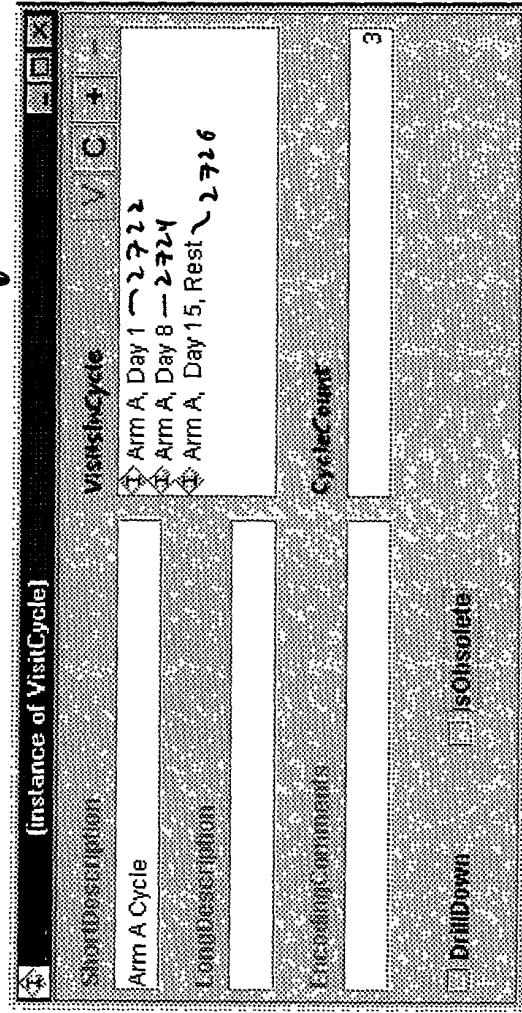
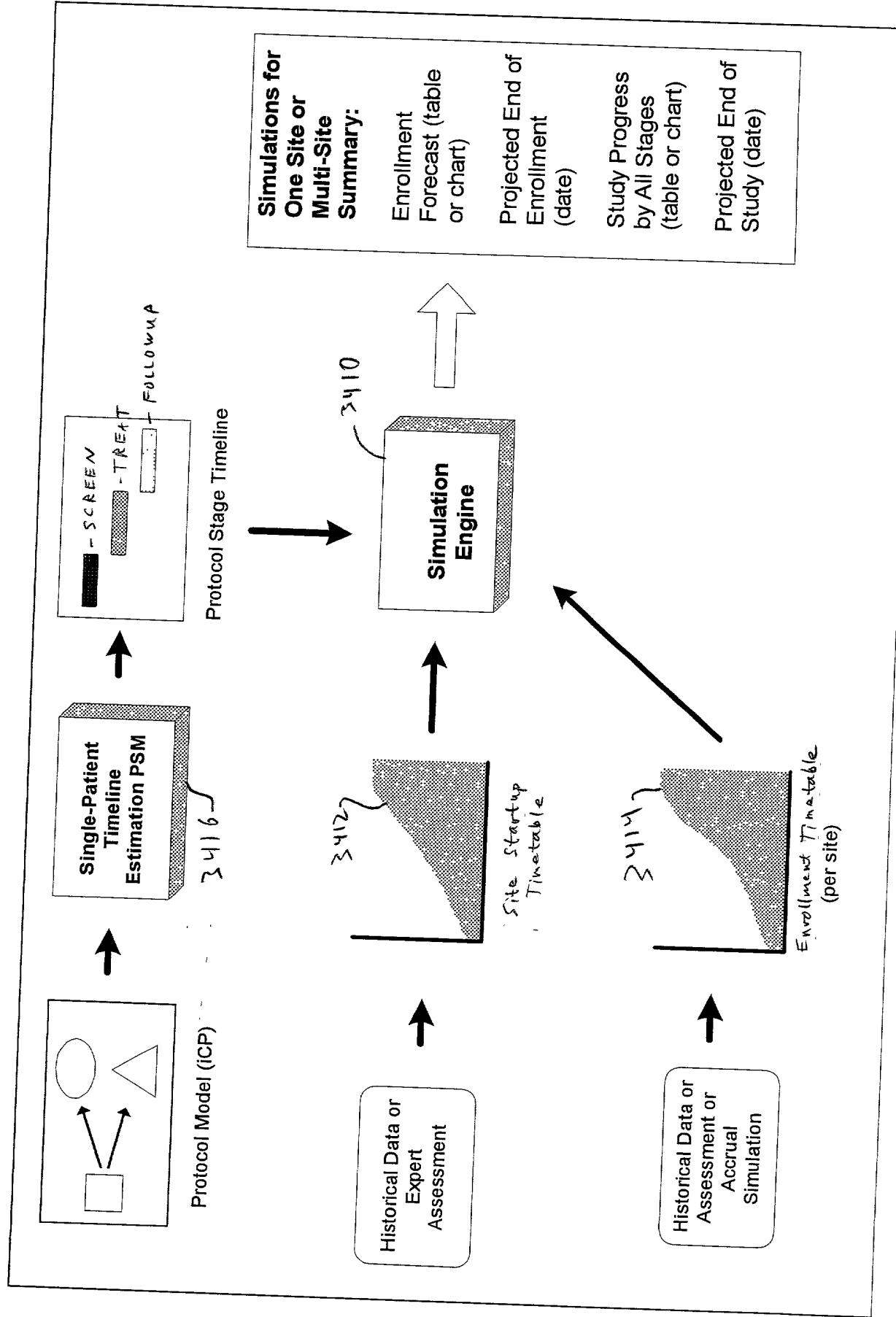


Fig. 33

# Timeline Simulation Process Flow



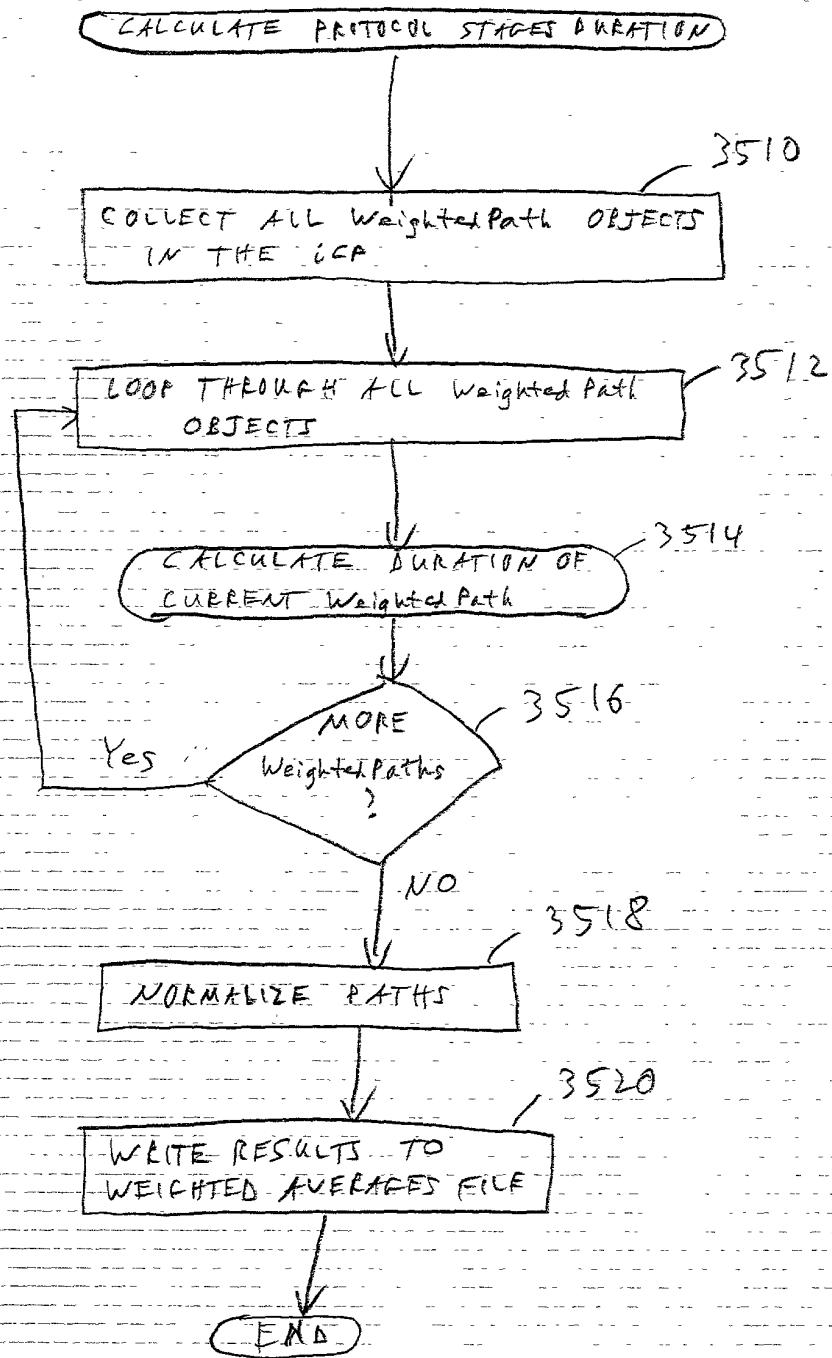


Fig.35

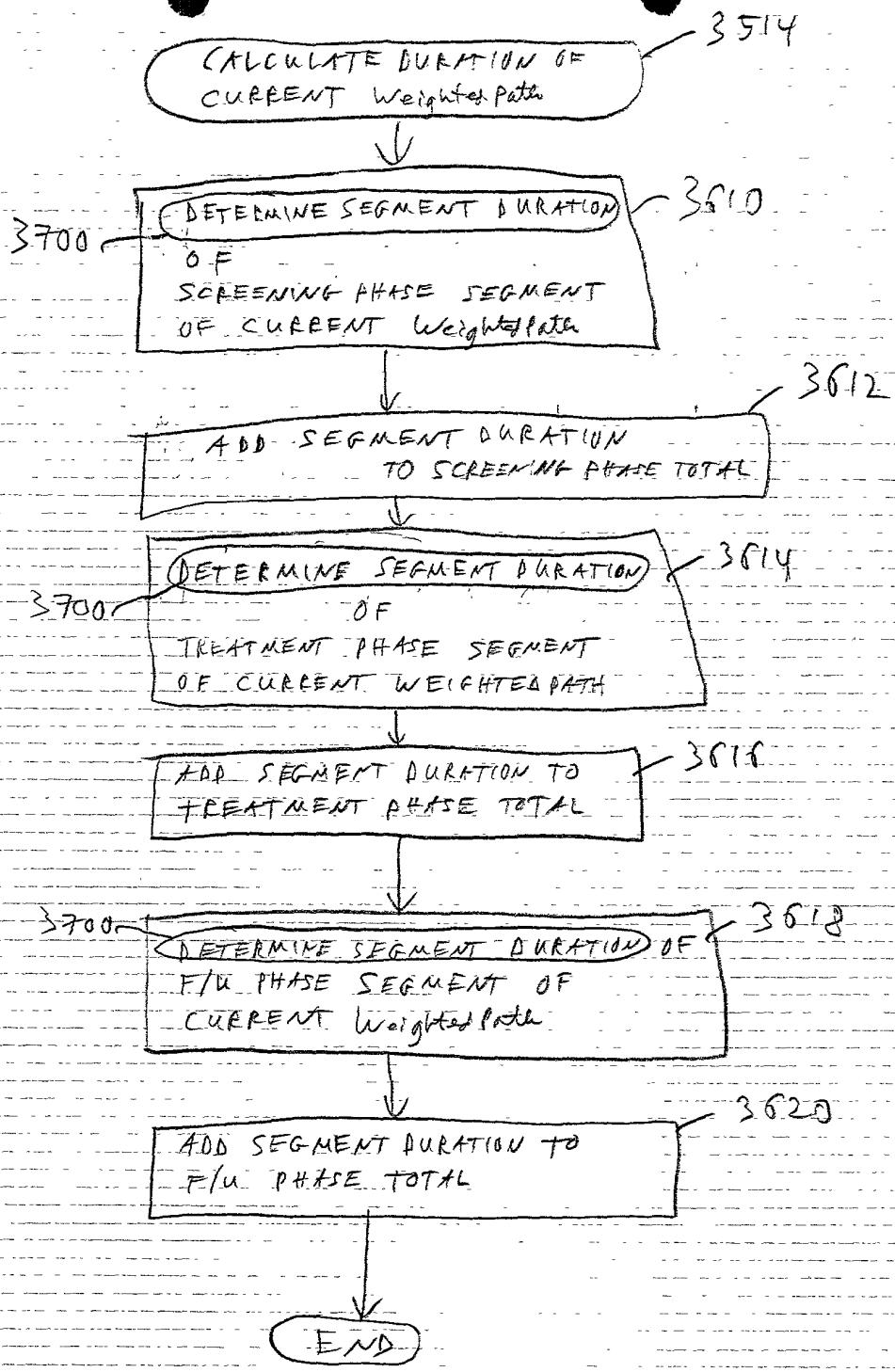


Fig. 36

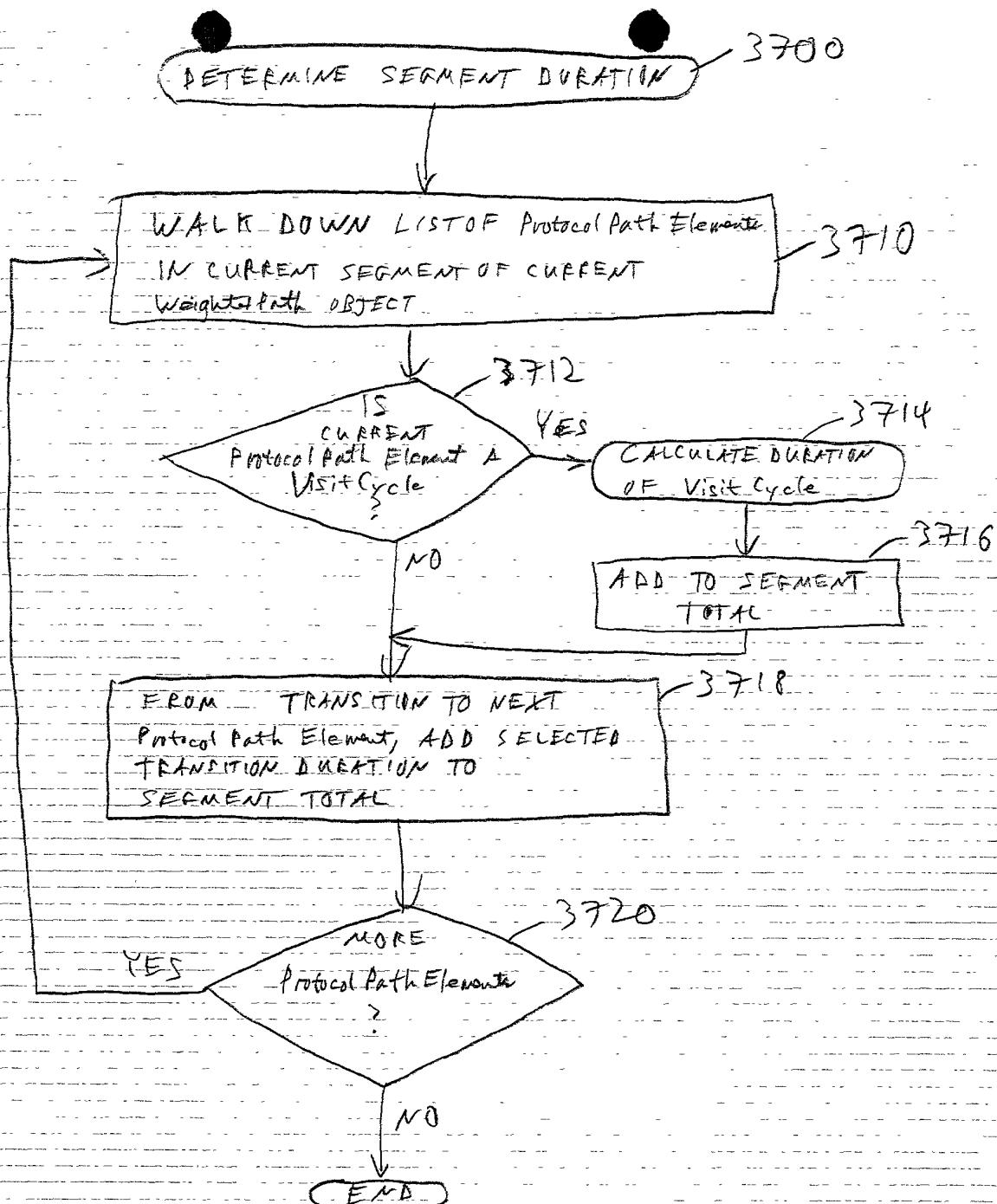


Fig. 37

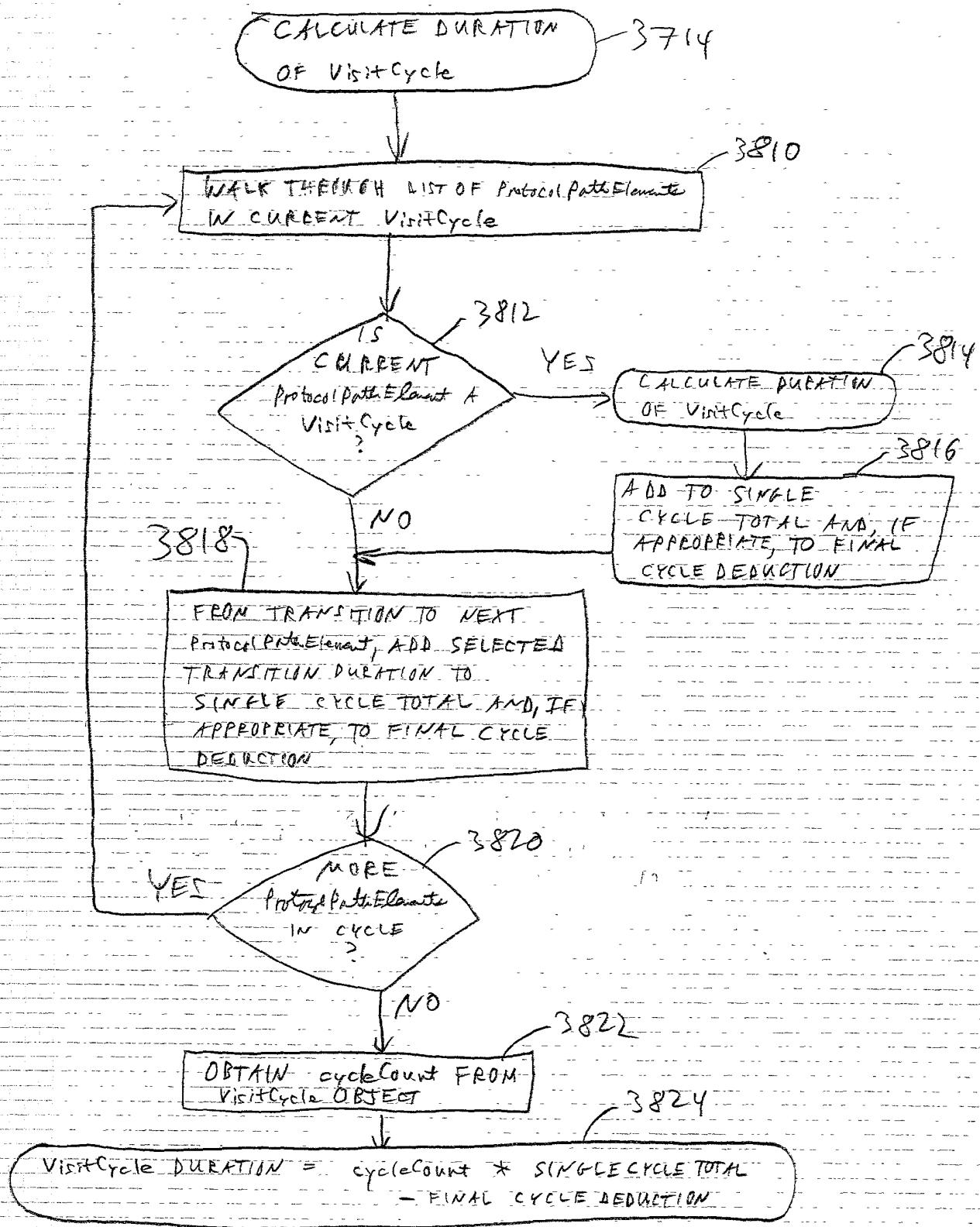


Fig. 38

Screening duration =  $7 + 7 = 14$   
 Treatment =  $3 * (1+1+1) - 1 + 7 + 7 = 22$   
 Follow up = 30

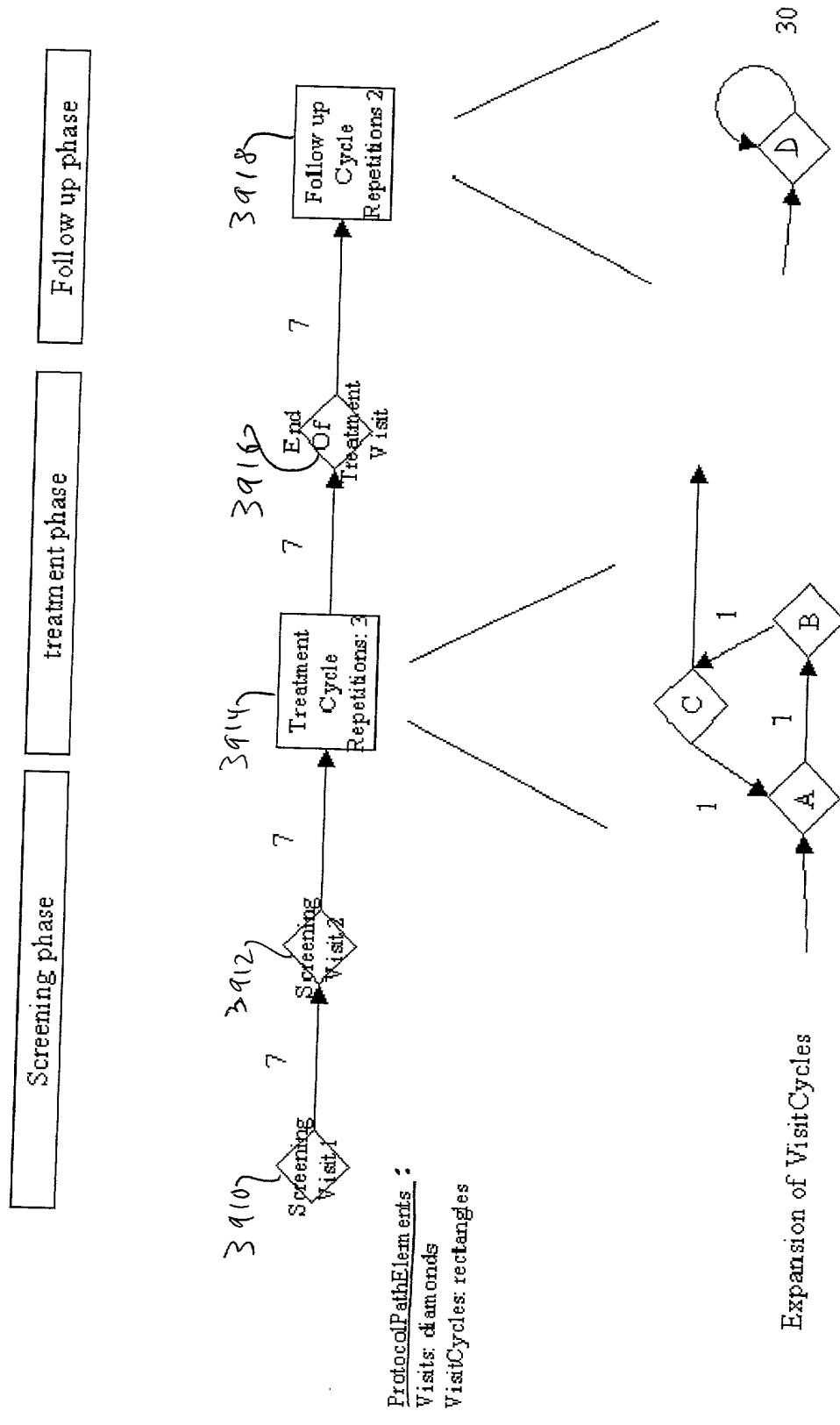
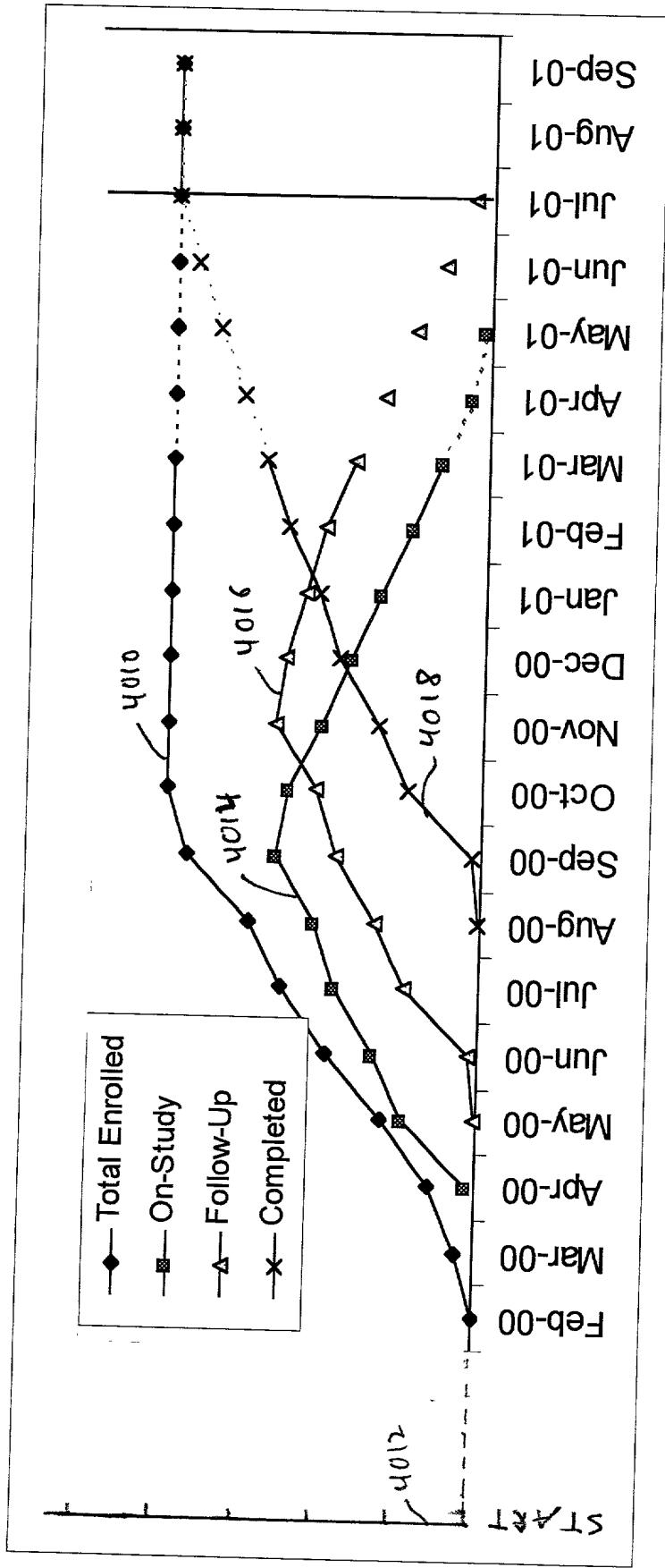


Fig. 39

# Forecast Trial Completion



*The last patient should complete followup in July 2001*

Fig. 40